No. 04-623

Title:	Alberto R. Gonzales, Attorney General, et al., Petitioners v. Oregon, et al.
Docketed:	November 9, 2004
Lower Ct:	United States Court of Appeals for the Ninth Circuit
Case Nos.:	(02-35587)
Decision Date:	May 26, 2004
Rehearing Denied:	August 11, 2004

Questions Presented

~~Date~~	~~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~~~~~
Nov 9 2004	Petition for a writ of certiorari filed. (Response due December 9, 2004)
Nov 9 2004	Appendix of John D. Ashcroft, Attorney General, et al. filed.
Dec 1 2004	Order extending time to file response to petition to and including January 10, 2005, for all respondents.
Dec 6 2004	Brief amicus curiae of Family and Family Research Council filed.
Jan 7 2005	Brief of respondents Oregon, et al. in opposition filed.
Jan 10 2005	Brief of respondents Patient-Respondents in opposition filed.
Jan 10 2005	Brief of respondents Peter Rasmussen and David Hochhalter in opposition filed.
Jan 26 2005	DISTRIBUTED for Conference of February 18, 2005.
Feb 2 2005	Reply of petitioners John D. Ashcroft, Attorney General, et al. filed. (Distributed)
Feb 22 2005	Petition GRANTED.
Mar 29 2005	Brief amici curiae of Family and Family Research Council filed.
Mar 31 2005	Extension of time within which to file the joint appendix and petitioners' brief on the merits to and including May 9, 2005.
May 2 2005	Motion to dispense with printing the joint appendix filed by petitioners.
May 5 2005	Brief amicus curiae of Liberty Counsel filed.
May 6 2005	Further extension of time within which to file the joint appendix and petitioners' brief on the merits to and including May 12, 2005.
May 6 2005	Brief amici curiae of United States Conference of Catholic Bishops, et al. filed.
May 9 2005	Brief amicus curiae of International Task Force on Euthanasia and Assisted Suicide filed.
May 9 2005	Brief amicus curiae of Americans United for Life filed.
May 9 2005	Brief amicus curiae of Thomas More Society filed.
May 9 2005	Brief amici curiae of Pro-Life Legal Defense of Life, et al. filed.

May 9 2005	Brief amicus curiae of National Association of Pro-Life Nurses filed.
May 9 2005	Brief amicus curiae of American Center for Law and Justice filed.
May 9 2005	Brief amici curiae of Not Dead Yet, et al. filed.
May 9 2005	Brief amicus curiae of National Legal Center for the Medically Dependent & Disabled, Inc. filed.
May 9 2005	Brief amici curiae of Christian Medical Association, et al. filed.
May 11 2005	Brief amici curiae of Rick Santorum, et al. filed.
May 11 2005	Brief amicus curiae of Catholic Medical Association filed.
May 12 2005	Brief of petitioners Alberto R. Gonzales, Attorney General, et al. filed.
May 12 2005	Brief amicus curiae of Physicians for Compassionate Care Education Foundation filed.
May 16 2005	Motion to dispense with printing the joint appendix filed by petitioners GRANTED.
Jun 6 2005	Extension of time within which to file respondents' briefs on the merits to and including July 18, 2005.
Jun 10 2005	Brief amici curiae of Healthlaw Professors filed.
Jul 15 2005	Further extension of time within which to file respondents' briefs on the merits to and including July 21, 2005.
Jul 15 2005	Brief of respondent Oregon filed.
Jul 15 2005	Brief amicus curiae of American College of Legal Medicine filed. (Distributed)
Jul 18 2005	Brief amici curiae of Magaret P. Battin, et al. filed. (Distributed)
Jul 18 2005	Brief amici curiae of Coalition of Medical Associations and Societies, et al. filed. (Distributed)
Jul 18 2005	Brief amicus curiae of Members of Oregon Congressional Delegation filed. (Distributed)
Jul 18 2005	Brief amicus curiae of Cato Institute filed. (Distributed)
Jul 18 2005	Brief amici curiae of American Civil Liberties Union and the ACLU of Oregon filed. (Distributed)
Jul 18 2005	Brief amici curiae of 52 Religious and Religious Freedom Organizations filed. (Distributed)
Jul 18 2005	Brief amicus curiae of American Public Health Association filed. (Distributed)
Jul 18 2005	Brief amici curiae of Professors of Law filed. (Distributed)
Jul 20 2005	CIRCULATED.
Jul 20 2005	Brief amicus curiae of Surviving Family Members filed. (Distributed).
Jul 20 2005	SET FOR ARGUMENT on Wednesday, October 5, 2005.
Jul 21 2005	Brief amici curiae of Autonomy, Inc. and Cascades AIDS Project filed. (Distributed).
Jul 21 2005	Brief of respondents Peter Rasmussen and David Hochhalter filed. (Distributed)
Jul 21 2005	Brief of Patient-Respondents filed.(Distributed)
Jul 21 2005	Brief amici curiae of California, et al. filed. (Distributed)
Jul 21 2005	Brief amicus curiae of Coalition of Mental Health Professionals filed. (Distributed).
Jul 29 2005	Record received from U.S.C.A. For 9th Circuit. (1 box)
Aug 5 2005	Motion for additional time to argue and for divided argument or in the alternative for divided argument filed by Patient-respondents.
Aug 11 2005	Motion for leave to intervene filed by Andrews, et al.
Aug 17 2005	Motion DISTRIBUTED for Conference of September 26, 2005.
Aug 19 2005	Record received from U.S.District Court for Dist. of Oregon. (3 boxes)
Aug 25 2005	Reply of petitioners Alberto R. Gonzales, Attorney General, et al. filed. (Distributed)
Sep 2 2005	Motion for additional time to argue and for divided argument by respondent DENIED.
Oct 3 2005	Motion for leave to intervene filed by respondent GRANTED. The Chief Justice took no part in the consideration or decision of this motion.
Oct 5 2005	Argued. For petitioners: Paul D. Clement, Solicitor General, Department of Justice, Washington, D.C. For respondents: Robert M. Atkinson, Senior Assistant Attorney General, Salem, Ore.

Supreme Court, U.S.
FILED
04-623 NOV 9 - 2004
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No.

In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

PAUL D. CLEMENT
Acting Solicitor General
Counsel of Record

PETER D. KEISLER
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

GREGORY G. KATSAS
Deputy Assistant Attorney General

DOUGLAS HALLWARD-DRIEMEIER
Assistant to the Solicitor General

MARK B. STERN
JONATHAN H. LEVY
Attorneys

Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

BEST AVAILABLE COPY

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States; Karen Tandy, Administrator of the Drug Enforcement Administration; Kenneth W. McGee, Assistant Special Agent-in-Charge of the Portland Office of the Drug Enforcement Administration; the United States of America; the United States Department of Justice; and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, David Malcolm Hochhalter, Richard Holmes, James Romney, Melissa Bush, and John Doe #1.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statutory provisions involved	2
Statement	2
Reasons for granting the petition	9
I. The Ninth Circuit erred in holding that a single State's law rendered invalid the Attorney General's reasonable interpretation of the Controlled Substances Act and its implementing regulations to bar the of controlled substances to facilitate suicide	11
A. The Attorney General's reasonable interpretation of the comprehensive federal statute must prevail over he determination by a particular State that departs radically from long-accepted legal and ethical norms	11
B. The Ninth Circuit's reliance on *Gregory* v. *Ashcroft* and related principles to defeat the application of federal law to the private conduct of dispensing drugs is fundamentally flawed	20
II. The Court of Appeals' decision warrants review because it conflicts with decisions of this Court and improperly allows states to dictate the content of federal law	26
Conclusion	28

TABLE OF AUTHORITIES

Cases:

Alliance for Cannabis Therapeutics v. *DEA*, 15 F.3d 1131 (D.C. Cir. 1994)	16-17
Auer v. *Robbins*, 519 U.S. 452 (1997)	12

Cases—Continued: Page

Chevron U.S.A. Inc. v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) 11-12
Dickerson v. *New Banner Inst., Inc.*, 460 U.S. 103 (1983) 19
Gately v. *Massachusetts*, 2 F.3d 1221 (1st Cir. 1993) 21
Gregory v. *Ashcroft*, 501 U.S. 452 (1991) 10, 20, 21
Hammer v. *Dagenhart*, 247 U.S. 251 (1918) 22
Jerome v. *United States*, 318 U.S. 101 (1943) 18
Linder v. *United States*, 268 U.S. 5 (1925) 20, 22
Minor v. *United States*, 396 U.S. 87 (1969) 22
Mississippi Band of Choctaw Indians v. *Holyfield*, 490 U.S. 30 (1989) 8, 18
NLRB v. *Natural Gas Util. Dist.*, 402 U.S. 600 (1971) 20
NLRB v. *Randolph Elec. Membership Corp.*, 343 F.2d 60 (4th Cir. 1965) 20
Raich v. *Ashcroft*, 352 F.3d 1222 (9th Cir. 2003), cert. granted, 124 S. Ct. 2909 (2004) 26
Reina v. *United States*, 364 U.S. 507 (1960) 22
Solid Waste Agency v. *United States Army Corps of Eng'rs*, 531 U.S. 159 (2001) 8
Thomas Jefferson Univ. v. *Shalala*, 512 U.S. 504 (1994) 12
United States v. *Daniel*, 3 F.3d 775 (4th Cir. 1993), cert. denied, 510 U.S. 1130 (1994) 18
United States v. *Darby*, 312 U.S. 100 (1941) 22
United States v. *Lot 5, Fox Grove*, 23 F.3d 359 (11th Cir. 1994), cert. denied, 513 U.S. 1076 (1995) 21
United States v. *Moore*, 423 U.S. 122 (1975) 3, 4, 9, 14, 17-18, 22, 25
United States v. *Norris*, 780 F.2d 1207 (5th Cir. 1986) 18

Cases—Continued: Page

United States v. *Oakland Cannabis Buyers' Coop.*:
190 F.3d 1109 (9th Cir. 1999), rev'd, 532 U.S. 483 (2001) 26
532 U.S. 483 (2001) 6, 10, 15, 16, 22
United States v. *Pelzer*, 312 U.S. 399 (1941) 19
United States v. *Turley*, 352 U.S. 407 (1957) 18
United States v. *Vamos*, 797 F.2d 1146 (2d Cir. 1986), cert. denied, 479 U.S. 1036 (1987) 18
Washington v. *Glucksberg*, 521 U.S. 702 (1997) 7, 12, 13

Constitution, statute and regulations:

U.S. Const. Art. I, § 8, Cl. 3 (Commerce Clause) 26
Controlled Substances Act, Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. 801 *et seq.*) 2
21 U.S.C. 801(1) 13, 24
21 U.S.C. 801(2) 23
21 U.S.C. 801(6) 19
21 U.S.C. 802(10) 2
21 U.S.C. 802(21) 2, 14
21 U.S.C. 811 4
21 U.S.C. 811(a) 14, 16
21 U.S.C. 812 4
21 U.S.C. 812(b) 14, 15
21 U.S.C. 812(b)(1) 16
21 U.S.C. 812(b)(1)(B) 3, 6, 10, 14
21 U.S.C. 812(b)(2)-(5) 14
21 U.S.C. 812(b)(2)(B) 3
21 U.S.C. 812(b)(3)(B) 3
21 U.S.C. 812(b)(4)(B) 3
21 U.S.C. 812(b)(5)(B) 3
21 U.S.C. 812(c) 3
21 U.S.C. 821 4
21 U.S.C. 822(a)(2) 2
21 U.S.C. 822(b) 2
21 U.S.C. 823(a)(1) 14, 24
21 U.S.C. 823(f) 2, 3, 8, 14, 24, 25

Statute and regulations:	Page
21 U.S.C. 823(f)(3)	8-9
21 U.S.C. 823(f)(4)	8-9, 25
21 U.S.C. 823(f)(5)	9, 2, 25
21 U.S.C. 824(a)(4)	2
21 U.S.C. 829	3, 4, 14
21 U.S.C. 829(a)	14
21 U.S.C. 829(c)	14
21 U.S.C. 830(b)(3)(A)(ii)	15
21 U.S.C. 841(a)(1)	2, 3
21 U.S.C. 871(b)	4
21 U.S.C. 877	8
21 U.S.C. 903	4
Harrison Act of 1914, ch. 1, 38 Stat. 785	21
21 U.S.C. 352(j)	27
21 U.S.C. 355(d)	27
42 U.S.C. 257a (1970)	25
42 U.S.C. 290bb-2a	25
42 U.S.C. 1320a-7(a)	27
42 U.S.C. 1320a-7(b)(6)(B)	27
42 U.S.C. 1320c-5(a)(1)	27
42 U.S.C. 1320c-5(b)	27
42 U.S.C. 1395y(a)(1)(A) (2000 & Supp. I 2001)	27
Cal. Health & Safety Code § 11362.5(b)(1)(A) (West Supp. 2001)	15, 16
Death With Dignity Act, Or. Rev. Stat. §§ 127.800 *et seq.* (2003)	2, 5
§ 127.800	5
§ 127.800(11)	5
§ 127.815	5
§ 127.815(d)	5
§ 127.820	5
§ 127.885(1)	5

Statute and regulations—Continued:	Page
21 C.F.R.:	
Section 1306.04	2, 11
Section 1306.04(a)	4, 15, 17
Section 1308.12(e)	17
28 C.F.R. 0.100(b)	4
Miscellaneous:	
66 Fed. Reg. 56,607 (2001)	7
H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1(1970)	23
http://www.dhs.state.or.us/publichealth/chs/pas/ar-tbl-4.cfm	17
Letter from Janet Reno, Attorney General of the United States, to Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998)	5
Health & Human Servs., *Medicare Benefit Policy Manual* (visited Nov. 5, 2004) <http://www.cms.hhs.gov/manuals/102_policy/bp102c 16.pdf>	7
Kevin F. O'Malley et al., *Federal Jury Practice and Instructions (Criminal)* (5th ed. 2000)	18

In the Supreme Court of the United States

No.

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
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v.

STATE OF OREGON, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Acting Solicitor General, on behalf of the Attorney General of the United States and the other federal parties, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-63a) is reported at 368 F.3d 1118. The order of the district court granting respondents' motion for a preliminary injunction (Pet. App. 64a-97a) is reported at 192 F. Supp. 2d 1077.

JURISDICTION

The judgment of the court of appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11,

2004 (Pet. App. 98a-99a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Controlled Substances Act (CSA or Act), Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. 801 *et seq.*) and the implementing regulation, 21 C.F.R. 1306.04, are set out in an appendix to this petition. Pet. App. 149a-161a. The relevant provisions of the Oregon Death with Dignity Act, Or. Rev. Stat. §§ 127.800 *et seq.* (2003), are also set out in the appendix. Pet. App. 162a-165a.

STATEMENT

1. a. The Controlled Substances Act, 21 U.S.C. 801 *et seq.*, establishes a comprehensive federal scheme to regulate controlled substances. The CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801 *et seq.*]." 21 U.S.C. 841(a)(1). Physicians and other practitioners who dispense[1] controlled substances must "obtain from the Attorney General a registration." 21 U.S.C. 822(a)(2). They may dispense controlled substances only "in the course of professional practice or research," 21 U.S.C. 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," 21 U.S.C. 822(b).

The CSA authorizes the Attorney General to deny or revoke the registration of a practitioner "if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f), 824(a)(4). In determining the "public interest" for registration purposes, the

[1] Under the CSA, the term "dispense" includes the issuance of a prescription by a practitioner as well as delivering a controlled substance directly to a patient. 21 U.S.C. 802(10).

Attorney General considers a number of factors including the registrant's compliance with federal, state, and local laws relating to controlled substances, 21 U.S.C. 823(f)(3) and (4), and "such other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). In addition, a physician who dispenses controlled substances outside the "accepted limits" of medical practice is subject to prosecution under 21 U.S.C. 841(a)(1). *United States* v. *Moore*, 423 U.S. 122, 142 (1975).

Under the CSA, each controlled substance is placed in one of five schedules, depending on whether the substance has a currently accepted medical use in treatment in the United States and the relative abuse potential of the substance. The Act imposes varying regulatory restrictions on controlled substances depending on the applicable schedule. Substances in Schedule I—the most restricted schedule—have "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B), and may not be prescribed by a physician. 21 U.S.C. 829. Human consumption of Schedule I controlled substances is permissible only in a research setting where the research has been approved by the Food and Drug Administration and the researcher has obtained from the Drug Enforcement Administration (DEA) a registration authorizing the specific research protocol. 21 U.S.C. 823(f). Substances in Schedules II through V have a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B)), and therefore may be dispensed for medical use. 21 U.S.C. 829.

When the CSA was enacted in 1970, Congress made an initial assignment of controlled substances to the schedules it believed appropriate. 21 U.S.C. 812(c). Congress authorized the Attorney General, in consultation with the Secretary of Health and Human Services, to add or remove substances or to transfer substances from one schedule to another based upon statutory criteria that take into account changes in

medical and scientific understanding and shifts in patterns of abuse. 21 U.S.C. 811, 812. In addition, Congress provided the Attorney General with broad authority to promulgate "rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. 821, and "any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the CSA, 21 U.S.C. 871(b). The Attorney General has delegated his functions under the Act to the Administrator of DEA. 28 C.F.R. 0.100(b).

States remain free to enact their own laws relating to controlled substances, such as their own criminal penalties, but state laws are preempted to the extent of any "positive conflict" between a provision of state law and the CSA such that the two "cannot consistently stand together." 21 U.S.C. 903.

b. When the CSA became effective in 1971, DEA's predecessor (the Bureau of Narcotics and Dangerous Drugs) issued regulations through notice-and-comment rulemaking to implement the Act. One of those regulations, now found at 21 C.F.R. 1306.04(a), requires that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." A purported prescription that is not issued "in the usual course of professional treatment or in legitimate and authorized research" does not qualify as a "prescription" for purposes of 21 U.S.C. 829 and, if issued knowingly, will subject the practitioner "to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. 1306.04(a). As this Court indicated in *Moore*, this legitimate medical purpose requirement is implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See *Moore*, 423 U.S. at 137-139 & n.13.

2. In November 1994, Oregon voters passed a ballot initiative referred to as the Oregon Death with Dignity Act (DWDA), Or. Rev. Stat. §§ 127.800 *et seq.* (2003). The DWDA allows the prescribing and dispensing of "medication" for the purpose of enabling an individual with a terminal disease to commit suicide. *Id.* § 127.800(11). It requires the physician prescribing or dispensing the lethal substance to ensure that the patient is a resident of Oregon, is competent, has a terminal disease, and is making a voluntary and informed decision to obtain the drugs for the purpose of ending his or her life. See *id.* §§ 127.800, 127.815. A second physician must also verify most of those facts. *Id.* §§ 127.815(d), 127.820. The DWDA provides that a physician who prescribes or dispenses a lethal amount or combination of drugs in accordance with the DWDA shall not, for that reason, "be subject to civil or criminal liability or professional disciplinary action." *Id.* § 127.885(1). Oregon is the only State in the Union that purports to authorize physician-assisted suicide.

3. In 2001, the Attorney General sought an opinion from the Office of Legal Counsel (OLC) in the Department of Justice on the question whether a prescription for a drug to assist in a person's suicide, as contemplated in Oregon's DWDA, is a valid prescription pursuant to the CSA and its implementing regulation.[2] On June 27, 2001, OLC issued a memorandum concluding that "assisting in suicide is not a

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[2] No interpretive rule had previously been issued by the Attorney General on this subject. The Administrator of the DEA had previously concluded that assisting suicide in accordance with the DWDA would violate the CSA, E.R. 17, but then-Attorney General Janet Reno reached a different conclusion, see Pet. App. 109a (quoting Letter from Janet Reno, Attorney General of the United States, to Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998)). Neither of those previous documents was published in the *Federal Register*.

'legitimate medical purpose' that would justify a physician's dispensing controlled substances consistent with the CSA." Pet. App. 130a; see *id.* at 106a-148a.

The OLC memorandum explained that "[t]he CSA establishes a uniform, nation-wide statutory scheme for regulating the distribution of controlled substances," Pet. App. 130a, and that this Court had held, in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), that a California voter initiative purporting to recognize a medical use for marijuana could not provide the basis for an implied "medical necessity" exception or defense in the CSA in the face of Congress's placement of marijuana on Schedule I, which is reserved for substances with "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B). Pet. App. 131a-133a. The OLC memorandum concluded that Oregon's ballot initiative likewise could not immunize a physician from prosecution or loss of registration under the CSA, if the Attorney General determined, pursuant to the regulatory authority granted to him in the CSA, that assisting an individual to commit suicide does not constitute a "legitimate medical purpose" for which controlled substances may be prescribed. *Id.* at 133a-134a.

The OLC memorandum also canvassed the views of medical and nursing associations, federal and state law, and judicial opinions and concluded, based on that review, that despite the Oregon voters' approval, physician-assisted suicide is not a "legitimate medical purpose." The memorandum noted that "state law and policy, with the sole exception of Oregon's, emphatically oppose assisted suicide," Pet. App. 117a, and that federal law likewise prohibits such conduct in federal medical facilities and denies federal financial assistance in support of it, *id.* at 119a-122a. For example, the memorandum noted that the Health Care Financing Administration in the Department of Health and Human Services had determined that physician-assisted suicide is not eligible

for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." *Id.* at 120a-121a (internal quotation marks omitted).[3] In addition, the OLC memorandum reviewed the position of leading organizations of the medical profession, including the American Medical Association, American Nurses Association, and American Psychiatric Association, all of which took the view that physician-assisted suicide was "fundamentally incompatible with the physician's role as healer." *Id.* at 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)).

On November 9, 2001, the Attorney General published an interpretive rule in the *Federal Register* (66 Fed. Reg. 56,607 (2001)), that adopted the analysis of the OLC Memorandum. Pet. App. 100a-105a. The Attorney General determined that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR § 1306.04," and therefore that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." *Id.* at 102a. The Attorney General made clear that these conclusions "appl[y] regardless of whether state law authorizes or permits such conduct by practitioners or others." *Ibid.*

4. The State of Oregon and others challenged the interpretive rule in the United States District Court for the District of Oregon. That court held the interpretive rule invalid and enjoined its application. Pet. App. 64a-97a. The Attorney General and the other federal parties appealed. The court of appeals first held that the district court had lacked

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[3] The Health Care Financing Administration is now called the Centers for Medicare and Medicaid Services (CMS). CMS maintains this policy at present, and it is currently reflected in the Health & Human Servs., *Medicare Benefit Policy Manual*, ch. 16, § 20 (visited Nov. 5, 2004) <http://www.cms.hhs.gov/ manuals/102_policy/bp102c16.pdf>.

jurisdiction over respondents' suit. *Id.* at 2a-3a & n.1, 56a-61a. Instead, the court of appeals treated the action as a petition for review under 21 U.S.C. 877 that had been mistakenly filed in district court and transferred to the court of appeals. Pet. App. 2a-3a & n.1. On the merits, a divided panel granted the petitions for review.

a. The majority concluded that the interpretive rule was invalid absent an "unmistakably clear" indication of congressional intent to regulate physician-assisted suicide, because, in the majority's view, the rule "invokes the outer limits of Congress' power" by altering "the usual constitutional balance between the States and the Federal Government." Pet. App. 12a-13a (quoting *Solid Waste Agency* v. *United States Army Corps of Eng'rs*, 531 U.S. 159, 172-173 (2001), and *Gregory* v. *Ashcroft*, 501 U.S. 452, 461 (1991) (internal quotes omitted)). The court also held that the interpretive rule violated "the plain language of the CSA," *id.* at 13a, which, according to the majority, (1) only addresses "drug abuse," *id.* at 13a-14a, (2) entrusts medical decisions to the Secretary of Health and Human Services (not the Attorney General), *id.* at 15a, and (3) requires the Attorney General to address all five statutory factors in Section 823(f) that are relevant to registration of a physician under the CSA, including, in particular, whether the physician's conduct complies with state law, before adopting an interpretive rule such as the one here at issue, *id.* at 16a. The panel granted the petitions for review and "continued" the district court's injunction. *Id.* at 25a.

b. Senior Judge Wallace dissented. Pet. App. 25a-63a. He relied upon the presumption that Congress does not make the application of federal statutes dependent on state law, *id.* at 36a (citing *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989)), and noted that, while a physician's compliance with state law is relevant under the CSA in determining whether his or her registration would

be consistent with the public interest, *id.* at 37a (citing 21 U.S.C. 823(f)(3) and (4)), other factors, including whether the physician's conduct "may threaten the public health and safety," are not dependent on state law, *ibid.* (citing 21 U.S.C. 823(f)(5)). The dissent further noted that, while the Secretary of Health and Human Services is specifically delegated certain functions under the CSA, responsibility under the Act for determining whether a physician's registration serves the public interest is assigned to the Attorney General alone. *Id.* at 39a-40a. The dissent also rejected the majority's suggestion that application of the CSA to the dispensing of controlled substances to assist suicide is at the limits of Congress's power or would alter federal-state relations, *id.* at 45a, and pointed out that, to the contrary, Congress's authority under the Commerce Clause to regulate the distribution of controlled substances is well-established, *id.* at 49a-50a. Finally, the dissent observed that the Attorney General's conclusion that physician-assisted suicide is not a legitimate medical purpose is well supported by an "overwhelming historical, legal, and medical consensus." *Id.* at 56a.

c. The court of appeals denied the government's petition for rehearing or rehearing en banc. Pet. App. 98a-99a

REASONS FOR GRANTING THE PETITION

The Ninth Circuit held in this case that the Attorney General's ability to administer and enforce the Controlled Substances Act is subordinate to the views of each of the 50 States regarding the permissible uses of scheduled substances. That holding is erroneous and stands the proper relationship between the federal and state governments under the Constitution on its head. Moreover, the court of appeals' ruling conflicts with this Court's recognition in *United States* v. *Moore*, 423 U.S. 122 (1975), that a physician's prescription violates the CSA unless made "in

the usual course of a professional practice and in accordance with a standard of medical practice *generally recognized and accepted in the United States*," *id.* at 139 (emphasis added). The court of appeals' ruling also conflicts with this Court's more recent decision in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), which gave effect to the determination set forth in the CSA that marijuana has "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B), in the face of a State's contrary determination of that disputed medical question, 532 U.S. at 486, 493.

The court of appeals reached this erroneous result only by misconstruing and dramatically expanding the scope of this Court's decision in *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), and by finding, contrary to this Court's well-established jurisprudence, that federal regulation of the distribution of controlled substances alters the usual constitutional balance between the States and the federal government because of its effect on the practice of medicine. By relying on constitutional avoidance principles to avoid a plainly reasonable interpretation of the CSA by the Attorney General, the court of appeals' holding threatens to undermine federal authority to regulate in numerous other areas that may have an effect on the practice of medicine. This Court's review is warranted to correct this serious misconception of the relative powers of state and federal governments under the Constitution and the CSA.

I. THE NINTH CIRCUIT ERRED IN HOLDING THAT A SINGLE STATE'S LAW RENDERED INVALID THE ATTORNEY GENERAL'S REASONABLE INTERPRETATION OF THE CONTROLLED SUBSTANCES ACT AND ITS IMPLEMENTING REGULATIONS TO BAR THE DISPENSING OF CONTROLLED SUBSTANCES TO FACILITATE SUICIDE

A. The Attorney General's Reasonable Interpretation Of The Comprehensive Federal Statute Must Prevail Over The Determination By A Particular State That Departs Radically From Long-Accepted Legal And Ethical Norms

The court of appeals acknowledged that the CSA prohibits practitioners from prescribing or dispensing controlled substances except for a "legitimate medical purpose" and "in the usual course of professional treatment." Pet. App. 5a (quoting 21 C.F.R. 1306.04). Thus, as the court of appeals recognized, the issue presented in this case is "who gets to decide," *id.* at 9a, whether a practitioner's conduct comports with that federal requirement under the CSA—the Attorney General, pursuant to a uniform national standard, or each of the 50 States, according to 50 different views regarding the proper use of controlled substances. The text and structure of the CSA, as well as general principles of federalism, compel the conclusion that the CSA, and the Attorney General's regulation implementing it, establish a single national standard.

1. In the interpretive ruling under challenge here, the Attorney General concluded that dispensing drugs to assist another individual in taking his or her life does not constitute a "legitimate medical purpose" in the course of medical "treatment." 21 C.F.R. 1306.04(a). Because the Attorney General has primary responsibility for enforcing the CSA, his interpretation of the Act is entitled to deference under

Chevron U.S.A. Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984), and his interpretation of his own regulation is entitled to even greater deference under *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997), and *Thomas Jefferson University* v. *Shalala*, 512 U.S. 504, 512 (1994). The Attorney General clearly acted reasonably in concluding that dispensing drugs to assist a person to commit suicide is not for a "legitimate medical purpose" or for "treatment" within the meaning of the CSA and his implementing regulation.

Indeed, the Attorney General's conclusion is the position maintained by 49 States, the federal government, and leading associations of the medical profession. As the Court noted in *Washington* v. *Glucksberg*, 521 U.S. 702 (1997), "[i]n almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide." *Id.* at 710. With specific reference to Oregon's DWDA, the Court made clear that the Oregon statute was contrary both to longstanding historical practices and to contemporary trends in the law. *Id.* at 717-718. Thus, contrary to the dominant theme of the court of appeals' decision, the Attorney General did not ignore the laws of the States in interpreting the CSA to bar the dispensing of controlled substances to facilitate suicide. His interpretation is consistent with the position of the overwhelming majority of the States.

Numerous health care experts have agreed that physician-assisted suicide is not a legitimate medical treatment. In *Glucksberg*, the Court noted that New York State's Task Force on Life and the Law—a commission composed of doctors, ethicists, lawyers, religious leaders and interested laypersons—had unanimously concluded that "[l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable. . . . [T]he potential dangers of this dramatic change in public policy would outweigh any benefit that might be achieved." 521

U.S. at 719 (quotation marks and citation omitted). Likewise, as the OLC memorandum noted, the American Medical Association, American Nurses Association, and American Psychiatric Association filed a joint brief in *Glucksberg* taking the position that physician-assisted suicide is "fundamentally incompatible with the physician's role as healer." Pet. App. 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)). Within the federal government as well, the Department of Health and Human Services' Health Care Financing Administration similarly has determined that physician-assisted suicide is not eligible for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." Pet. App. 120a-121a (internal quotes omitted).

There can be no question, then, that the Attorney General's interpretive ruling is consistent with the prevailing views regarding medical practice and on that basis is, at the very least, reasonable and entitled to deference.

2. It is also clear, from the text and structure of the CSA, that the Attorney General's responsibility for enforcing the CSA required him to resolve the question whether the use of controlled substances to facilitate suicide is a "legitimate medical purpose" for "treatment." The principle that controlled substances may be dispensed only for a "legitimate medical purpose" in "treatment" is central to the CSA and is reflected throughout its provisions. The starting point of the Act (indeed, its first provision) is the recognition that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. 801(1). The federal regulatory scheme is built upon the dual principles that the dispensing of controlled substances should be allowed for such "legitimate

medical purposes" but that distribution for illegitimate purposes should be prohibited.

The Attorney General is charged under the CSA, 21 U.S.C. 811(a), with assigning a controlled substance to the appropriate "schedule" according to whether it has a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b), as well as with ensuring that there is an "adequate * * * supply" of Schedule I and Schedule II substances "for legitimate medical, scientific, research, and industrial purposes," 21 U.S.C. 823(a)(1). Those substances for which the Attorney General has determined there is "no currently accepted medical use in treatment in the United States" are placed in Schedule I, 21 U.S.C. 812(b)(1)(B), and may not be prescribed or dispensed except pursuant to a research protocol specifically approved by the Attorney General and the Secretary of Health and Human Services with respect to the medical merits of the proposal and its security against diverting the substance from "legitimate medical or scientific use," 21 U.S.C. 823(f). Substances in other Schedules may be dispensed by practitioners only because they have "a currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)-(5), and a legitimate "medical use" in "treatment" therefore is a prerequisite to such dispensing.

Other provisions of the Act also confine a practitioner's latitude in dispensing drugs on Schedules II through V to legitimate medical uses in the course of treatment. See, *e.g.*, 21 U.S.C. 829(c) ("No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose."); *Moore*, 423 U.S. at 137 n.13 (indicating that the same requirement is implicit in 21 U.S.C. 829(a) for Schedule II substances). The Act authorizes the prescription of controlled substances only by a practitioner acting "in the course of professional practice or research," 21 U.S.C. 802(21), and, as a general matter, only by written

"prescription," 21 U.S.C. 829. The Attorney General's unchallenged regulation clarifies that a prescription, to be valid, must be "for a legitimate medical purpose" and issued "in the usual course of professional treatment or in legitimate and authorized research." 21 C.F.R. 1306.04(a). Certain reporting requirements imposed by the CSA similarly define a "valid prescription" as one "issued for a legitimate medical purpose by an individual practitioner * * * acting in the usual course of the practitioner's professional practice," 21 U.S.C. 830(b)(3)(A)(ii).

3. a. The centrality of the concepts of "legitimate medical purpose" and medical "treatment" in the text and structure of the CSA leaves no doubt that those standards are to be established and enforced at the federal, rather than state, level. This Court's decisions confirm that conclusion. There is no question, for example, that the determination whether a drug has a "currently accepted medical use in treatment in the United States," for purposes of scheduling the substance under 21 U.S.C. 812(b), is a federal decision that is binding on the States, rather than vice-versa. In *Oakland Cannabis*, the voters in California had passed a ballot initiative that established, for purposes of state law, that seriously ill Californians could "use marijuana for medical purposes." 532 U.S. at 486 (quoting Cal. Health & Safety Code Ann. § 11362.5(b)(1)(A) (West Supp. 2001)). Nonetheless, this Court rejected the marijuana cooperative's reliance on the state law as supporting a "medical necessity" defense to prosecution under the CSA. The Court held that such a defense would be inconsistent with Congress's finding, in classifying marijuana in Schedule I, that it has "no currently accepted medical use in treatment in the United States." *Id.* at 492. See *id.* at 493 (notwithstanding state law, "Congress has made a determination that marijuana has no medical benefits worthy of an exception," and the Court

could not "override a legislative determination" to that effect).

Although Congress, rather than the Attorney General, made the determination whether marijuana has a generally accepted medical use in treatment, a determination by the Attorney General would be no less binding on the States. The CSA expressly grants the Attorney General authority to assign substances to the appropriate schedule, and to move substances—including those originally classified by Congress—among schedules. 21 U.S.C. 811(a). In fact, in *Oakland Cannabis*, the Court specifically recognized that "[t]he Attorney General can include a drug in schedule I * * * if the drug 'has no currently accepted medical use in treatment in the United States,'" 532 U.S. at 492 (quoting 21 U.S.C. 812(b)(1)), and one issue raised in the case was whether Congress's assignment of marijuana to Schedule I, without making specific findings about its medical usefulness, was entitled to as much deference as the Attorney General's assignment would be. *Ibid.* The Court specifically rejected the challenge to Congress's classification of marijuana, holding that "the statute consistently treats all schedule I drugs alike," whether placed there by Congress or the Attorney General. *Id.* at 492-493.

Just as California's ballot initiative purporting to recognize a "use [for] marijuana for medical purposes," Cal. Health & Safety Code § 11362.5(b)(1)(A) (West Supp. 2001), did not compel recognition in *Oakland Cannabis* of an *exception* to the currently applicable rule under the CSA that a Schedule I substance has no "currently accepted medical use in treatment in the United States," neither would the state law be binding on the Attorney General for purposes of compelling him to *reclassify* marijuana to a different schedule under the CSA. Rather, such a determination must be based upon an independent *federal* assessment of the medical and scientific evidence and, if supported

by substantial evidence, is binding upon the entire Nation for purposes of the CSA. See *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131 (D.C. Cir. 1994) (upholding DEA's refusal to reschedule marijuana as supported by substantial evidence). As the D.C. Circuit held in *Alliance for Cannabis*, "only rigorous scientific proof can satisfy the CSA's 'currently accepted medical use' requirement." *Id.* at 1137. There is no basis in the CSA for substituting a ballot initiative, such as California voters' approval of medical marijuana or Oregon voters' endorsement of physician-assisted suicide, for the requisite "rigorous scientific proof" regarding a substance's "accepted medical use."

Nor is there any reason to conclude, as the Ninth Circuit in this case did, that the Attorney General's determination whether a *particular* use of a controlled substance constitutes a "legitimate medical use" "in the usual course of professional treatment," 21 C.F.R. 1306.04(a), is any less binding in the States for purposes of the CSA than his determination whether a substance has *any* accepted medical use. If, as is evident from *Oakland Cannabis*, the Attorney General could reclassify the Schedule II substances used by Oregon physicians to assist suicide[4] to Schedule I if the medical and scientific evidence warranted—despite the passage of the assisted suicide initiative in Oregon—then he likewise can determine that, while those Schedule II substances have *other* generally accepted medical uses in treatment, deliberately assisting a person to commit suicide is not one.

This Court's decision in *Moore* strongly supports that conclusion. *Moore* involved the prosecution of a physician who

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[4] According to the Oregon Department of Human Services, the three drugs dispensed pursuant to the DWDA are secobarbital, pentobarbital, and amobarbital, all of which are Schedule II depressants. See http://www.dhs.state.or.us/publichealth/chs/pas/ar-tbl-4.cfm; 21 C.F.R. 1308.12(e).

prescribed large quantities of methadone tablets with little or no medical assessment or supervision. See 423 U.S. at 126. He was convicted under the CSA for prescribing controlled substances outside the usual course of his professional practice. This Court held that the CSA was intended to limit a physician's distribution of controlled substances to actions "as a physician" and in the course of "professional practice." 423 U.S. at 140, 141. The Court made clear that Moore's conviction, which it affirmed, was based on a uniform nationwide standard for deciding whether the prescriptions were valid and permissible under the CSA: whether they were "in accordance with a standard of medical practice generally recognized and accepted *in the United States.*" *Id.* at 139 (quoting jury instructions) (emphasis added).[5]

b. The conclusion evident from the text and structure of the CSA—that Congress intended the Act to be applied in a uniform manner across the Nation—is further confirmed by the well-established principle of statutory construction that, "in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43, 47 (1989) (quoting *Jerome* v. *United States*, 318 U.S. 101, 104 (1943), and holding that the word "domicile" used in a federal law should have a uniform meaning and is not defined by

[5] With the exception of the decision below, the courts of appeals have followed *Moore* and applied a national standard for professional practice under the CSA. See *United States* v. *Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986) (standard of professional practice "generally recognized and accepted in the United States"), cert. denied, 479 U.S. 1036 (1987); *United States* v. *Norris*, 780 F.2d 1207, 1209 & n.2 (5th Cir. 1986) (same); *United States* v. *Daniel*, 3 F.3d 775, 778 (4th Cir. 1993) (same), cert. denied, 510 U.S. 1130 (1994); Kevin F. O'Malley et al., *Federal Jury Practice and Instructions (Criminal)* § 64.16, at 423 (5th ed. 2000) (same).

state law). See *United States* v. *Turley*, 352 U.S. 407 (1957) (word "stolen," used in federal criminal statute, has a uniform nationwide meaning and is not defined by state law); *United States* v. *Pelzer*, 312 U.S. 399 (1941) (same for phrase "future interests" in federal tax statute). Nothing in either the CSA or its implementing regulation makes the definition of "legitimate medical purpose" depend upon state law. To the contrary, there are strong indications, as *Moore* and *Oakland Cannabis* recognize, that Congress did *not* intend the concepts of legitimate medical purpose, medical treatment, or public health and safety to be determined solely by reference to state law.

The *Mississippi Band* presumption is particularly appropriate with respect to the CSA. Congress made clear that it intended the CSA to establish a national, comprehensive, and uniform law governing the use of controlled substances in this country. The need for national control was so great that Congress specifically found it necessary to regulate purely intrastate conduct relating to controlled substances. See 21 U.S.C. 801(6) (finding that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic"). Thus, as in *Mississippi Band*, the application of federal law must not (and does not) depend on state law because "the application of federal legislation is nationwide and at times the federal program would be impaired if state law were to control." *Dickerson* v. *New Banner Inst., Inc.*, 460 U.S. 103, 119-120 (1983). If, for example, one State's voters were of the view that marijuana has a medical use in treating mild depression, and that view was binding on the Attorney General for purposes of scheduling and ensuring adequate supplies for legitimate medical uses, the federal scheme to control the lines of distribution of that drug—including in other States that did not share the maverick view—would be severely undermined. The CSA's

scheme to control *all* manufacturing, possession, and distribution of any scheduled drug unquestionably constitutes "federal legislation, administered by a national agency, intended to solve a national problem on a national scale," the success of which cannot depend upon the vagaries of state law. *NLRB* v. *Natural Gas Util. Dist.*, 402 U.S. 600, 603-604 (1971) (quoting *NLRB* v. *Randolph Elec. Membership Corp.*, 343 F.2d 60, 63 (4th Cir. 1965)).

B. The Ninth Circuit's Reliance On *Gregory* v. *Ashcroft* And Related Principles To Defeat The Application Of The CSA To Private Conduct In Dispensing Drugs Is Fundamentally Flawed

1. The court of appeals failed to follow *Oakland Cannabis*, *Moore*, and *Mississippi Band*, and instead concluded that this Court's decision in *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), compelled a holding that state law controls the question whether a physician's conduct is for a legitimate medical purpose under the CSA. The court of appeals even went so far as to conclude that the Attorney General's interpretive ruling that dispensing a federally controlled substance to assist a person to commit suicide is not permitted under the CSA "invokes the outer limits of Congress's power by encroaching on state authority to regulate medical practice." Pet. App. 12a (citing *Linder* v. *United States*, 268 U.S. 5, 18 (1925)). Because, in the court of appeals' view, the effect of the CSA on Oregon law "alter[s] the usual constitutional balance between the States and the Federal Government" by exercising control over "an area of law traditionally reserved for state authority," *id.* at 11a (quoting *Gregory*, 501 U.S. at 461 (additional internal quotes omitted)), the court required that the CSA make "unmistakably clear" the Attorney General's authority to adopt the interpretive rule, *ibid.*

The court of appeals' conclusion that federal regulation of the distribution of controlled substances "alter[s] the usual constitutional balance between the States and the Federal Government" in a manner that requires an "unmistakably clear" statement by Congress fundamentally misunderstands the constitutional rule. The decision in *Gregory* turned on the fact that the federal statute at issue threatened to intrude upon a State's determination of the qualifications of its own judges, which this Court characterized as a constitutionally protected "decision of the most fundamental sort for a sovereign entity." 501 U.S. at 460. As the courts of appeals have recognized, *Gregory* must be limited to such basic threats to state sovereignty. See *United States* v. *Lot 5, Fox Grove*, 23 F.3d 359, 362 (11th Cir. 1994) (noting that "the *Gregory* plain statement preemption rule is limited to federal laws impacting a state's self-identification as a sovereignty"), cert. denied, 513 U.S. 1076 (1995); *Gately* v. *Massachusetts*, 2 F.3d 1221, 1230 (1st Cir. 1993) (noting that *Gregory* is limited to protecting "a core function going to the 'heart of representative government'"). The *Gregory* principle does not apply to the effect an Act of Congress may have on a State's views about *private* conduct that is otherwise within the scope of Congress's power to regulate. Furthermore, there is no merit to the court of appeals' notion that the application of the CSA here encroaches on "an area of law traditionally reserved for state authority," Pet. App. 11a, because, as *Glucksberg*, makes clear, there *is* no tradition of States authorizing physician-assisted suicide, 521 U.S. at 710.

The court of appeals' suggestion that Congress's regulation of the distribution of controlled substances in these circumstances raises significant constitutional problems also flies in the face of history and this Court's precedent. Congress has regulated prescriptions for controlled substances nationwide for almost a century under the CSA and its pre-

decessor, the Harrison Act of 1914, ch. 1, 38 Stat. 785. The court of appeals cited *Linder* as authority for the proposition that "direct control of medical practice in the states is beyond the power of the federal government," Pet. App. 10a, and for the further conclusion that the Attorney General's interpretive ruling "invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice," *id.* at 12a. Notably, the Court's *Lochner*-era decision in *Linder* relied upon the then-prevailing view, articulated in such cases as *Hammer* v. *Dagenhart*, 247 U.S. 251 (1918), that Congress could not employ its enumerated powers to accomplish more general purposes relating to health and welfare that were believed to be the exclusive province of the States. *Linder*, 268 U.S. at 17 (citing *Hammer*, among others, for the proposition that "an act of Congress ostensibly enacted under power granted by the Constitution, not naturally and reasonably adapted to the effective exercise of such power but solely to the achievement of something plainly within power reserved to the States, is invalid and cannot be enforced"). That holding of *Hammer* was expressly overruled in *United States* v. *Darby*, 312 U.S. 100, 115-117 (1941), which upheld the authority of Congress to regulate interstate commerce for the purpose of improving the working conditions of laborers, *id.* at 115.

Moreover, this Court's subsequent decisions establish that *Linder*'s suggestion that the federal government could not supplant wholesale the States' "control of medical practice" does not preclude federal regulation of interstate commerce in controlled substances despite the effects such regulation may have on unorthodox practices by physicians. See *Oakland Cannabis*, 532 U.S. at 492-493 (upholding CSA determination that marijuana lacked an acceptable medical use); *Moore*, 423 U.S. at 143 (affirming federal criminal conviction of physician engaged in unauthorized "experiment[al] * * * theory of detoxification"); *Minor* v. *United States*, 396 U.S. 87, 98 n.13 (1969) (ban on sale of narcotics is within Congress's constitutional power); *Reina* v. *United States*, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws").

Thus the court of appeals erred in concluding that the Attorney General's adoption of a national rule regarding the distribution of controlled substances to facilitate suicide upset the usual balance between the state and federal governments.

2. The other reasons the court of appeals gave in support of its holding are likewise flawed and are, to a significant degree, infected with the court of appeals' erroneous view that *Gregory*'s clear statement rule provided the applicable standard. Under the appropriate framework of affording *Chevron* deference to the Attorney General's construction of the CSA, rather than *Gregory*'s reverse presumption, none of the court of appeals' other points undermines the reasonableness of the Attorney General's interpretive ruling.

a. The court of appeals erred, for example, in relying on the notion that Congress intended "to limit federal authority under the CSA to the field of drug abuse," Pet. App. 14a, and that the CSA's "legitimate medical purpose" requirement must be construed to address that concern alone. In the first place, the taking of drugs to commit suicide *is* "drug abuse," and prohibiting the dispensing of a drug to facilitate suicide therefore falls within the purposes of the Act even as the court of appeals understood them. Moreover, Congress expressly stated broad goals in enacting the CSA, which was designed to combat "illegal importation, manufacture, distribution, and possession and *improper use* of controlled substances." 21 U.S.C. 801(2) (emphasis added). There is no doubt that Congress viewed the use of controlled substances to commit suicide to be a form of improper use. Congress specifically referred to the "[m]isuse of a drug in suicides and attempted suicides," and noted that "injuries resulting from

unsupervised use are regarded as indicative of a drug's potential for abuse." H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1., at 35 (1970). See *id.* at 34 (potential for abuse indicated by "evidence that individuals are taking the drug * * * in amounts sufficient to create a hazard to their health"); 21 U.S.C. 801(1) (noting congressional purpose "to maintain the health and general welfare of the American people"); 21 U.S.C. 823(f)(5) (requiring the Attorney General to consider threats to "the public health and safety" in issuing and revoking registrations to physicians to distribute controlled substances).

b. The court of appeals also cited the role of the Secretary of Health and Human Services as a reason why the Attorney General was not the appropriate officer within the federal government to make determinations under the CSA that affect the practice of medicine. Pet. App. 15a. While it is true that the CSA assigns certain functions with respect to its implementation to the Secretary, the Attorney General shares a role in many of those functions. *E.g.*, 21 U.S.C. 823(f) (assigning to both the Secretary and Attorney General roles in assessing proposed research projects relating to Schedule I drugs). Many other responsibilities under the CSA that require making determinations respecting the legitimate medical use of substances are assigned to the Attorney General alone. *E.g.*, 21 U.S.C. 823(a)(1) (Attorney General to ensure adequate supply of Schedule II substances for "legitimate medical * * * purposes"); 21 U.S.C. 823(f)(5) (listing "the public health and safety" among factors the Attorney General may consider in determining whether to revoke a practitioner's registration under the CSA). In any event, the determination whether dispensing drugs to facilitate suicide constitutes a "legitimate medical purpose" turns on an interpretation of the CSA and a regulation of the Attorney General, and does not require an assessment of

medical or scientific evidence of the sort that the CSA has assigned to the Secretary.[6]

c. The court of appeals' conclusion that the Attorney General violated 21 U.S.C. 823(f) by failing to consider all of the factors addressed in that section is also flawed. As an initial matter, Section 823(f) applies, by its terms, only to actions by the Attorney General to deny or revoke a CSA registration. The Attorney General's ruling at issue here is not such a denial or revocation. It is, rather, an interpretation of the *substantive* provisions of the Act, violation of which may in turn lead to a revocation of registration. In any event, Section 823(f) requires the Attorney General to consider a number of factors, including not only compliance with state laws, 21 U.S.C. 823(f)(4), but others, such as "[c]ompliance with applicable * * * Federal * * * laws relating to controlled substances," 21 U.S.C. 823(f)(4), and any threat to "the public health and safety," 21 U.S.C. 823(f)(5), that plainly call for an independent determination by the Attorney General. The court of appeals' ruling would preclude the Attorney General from exercising his statutory responsibility to ascertain whether a physician's registration is consistent with the public interest by making one factor—compliance with state law—determinative of that question. Indeed the court of appeals would make state law determinative of the question whether dispensing drugs to facilitate suicide even violates the CSA to begin with. There

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[6] The court of appeals cited (Pet. App. 15a) this Court's reference in *Moore* to the Secretary's function in determining "the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction." 423 U.S. at 144 (quoting 42 U.S.C. 257a (1970) (currently 42 U.S.C. 290bb-2a)). That provision is not directly at issue here, and the fact that certain health-related determinations are assigned to the Secretary does not negate the Attorney General's independent responsibilities under the CSA to ensure that controlled substances are prescribed only for a "legitimate medical purpose."

is no support in the statute's text for those extraordinary conclusions.

II. THE COURT OF APPEALS' DECISION WARRANTS REVIEW BECAUSE IT CONFLICTS WITH DECISIONS OF THIS COURT AND IMPROPERLY ALLOWS STATES TO DICTATE THE CONTENT OF FEDERAL LAW.

The court of appeals' decision warrants review by this Court. The holding below is yet another in a series of decisions in which the Ninth Circuit has undermined the federal government's ability to enforce the comprehensive federal law to control dangerous substances by subordinating federal authority to that of the States. In *Oakland Cannabis*, the Ninth Circuit held that in light of California's medical marijuana initiative, the United States could not enforce the CSA against individuals who purport to use marijuana for medical purposes, despite the federal determination in the CSA itself that no generally accepted medical use exists for marijuana. *United States* v. *Oakland Cannabis Buyers' Coop.*, 190 F.3d 1109, 1111, 1114 (9th Cir. 1999), rev'd, 532 U.S. 483 (2001). More recently, in *Raich* v. *Ashcroft*, 352 F.3d 1222 (2003), cert. granted, 124 S. Ct. 2909 (2004), the Ninth Circuit held that Congress could not, pursuant to the Commerce Clause (U.S. Const. Art. 1, § 8, Cl. 3), regulate "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law," because, in the court's view, that sub-class of activity did not have a sufficient impact on interstate commerce. 352 F.3d at 1228, 1231.

The Ninth Circuit's decision in this case is equally dismissive of the comprehensive federal regulatory scheme. It makes that scheme for controlling substances depend not on a uniform national standard, but on the vagaries of each State's notions of what constitutes a "legitimate medical

purpose" or "treatment," no matter how far outside the mainstream of accepted medical practice a particular State's views may be.

Moreover, the reasoning by which the court of appeals reached that conclusion is dramatic in its potential scope—as evidenced by its reliance on a *Lochner*-era case as defining the limits on Congress's authority to regulate matters that may indirectly affect the practice of medicine. The court of appeals' failure to apply this Court's presumption of national uniformity established in *Mississippi Band* and its invocation, instead, of the *Gregory* v. *Ashcroft* clear statement rule based on the mere fact that the practice of medicine is implicated could have far-reaching consequences if applied to other federal statutory schemes. *E.g.*, 21 U.S.C. 355(d) (requiring FDA to deny application for new drug if not safe and effective for its intended purpose); 21 U.S.C. 352(j) (drug is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"); 42 U.S.C. 1320a-7(a) and (b)(6)(B) (authorizing Secretary to exclude from participation in "any Federal health care program" a doctor (or anyone else) who furnishes services "substantially in excess of the needs of * * * patients," regardless of whether those patients were eligible for or participated in any federal programs); 42 U.S.C. 1320c-5(a)(1) and (b) (requiring any "health care practitioner" participating in Medicare to provide only "medically necessary" services to Medicare beneficiaries, and allowing the Secretary to bar violators from participating in the Medicare program); 42 U.S.C. 1395y(a)(1)(A) (2000 & Supp. I 2001) (authorizing Medicare to reimburse only "reasonable and necessary" medical services).

In short, Congress often attaches consequences under federal statutes to a determination by a federal official regarding what constitutes proper, necessary, safe, or effective

medical care. The uniform application of such statutory schemes is cast into doubt by the court of appeals' decision in this case.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

PAUL D. CLEMENT
Acting Solicitor General

PETER D. KEISLER
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

GREGORY G. KATSAS
Deputy Assistant Attorney General

DOUGLAS HALLWARD-DRIEMEIER
Assistant to the Solicitor General

MARK B. STERN
JONATHAN H. LEVY
Attorneys

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In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

OREGON, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

PAUL D. CLEMENT
Acting Solicitor General
Counsel of Record

PETER D. KEISLER
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

GREGORY KATSAS
Deputy Assistant Attorney General

DOUGLAS HALLWARD-DRIEMEIER
Assistant to the Solicitor General

MARK B. STERN
JONATHAN H. LEVY
Attorneys

Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

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TABLE OF CONTENTS

	Page
Appendix A (court of appeals opinion, filed May 26, 2004)	1a
Appendix B (district court opinion & order, filed Apr. 17, 2002)	64a
Appendix C (court of appeals rehearing, filed Aug. 11, 2004)	98a
Appendix D (Attorney General's interpretive ruling dated Nov. 9, 2001)	100a
Appendix E (Office of Legal Counsel memorandum, dated June 27, 2001)	106a
Appendix F (federal statutory provisions)	149a
Appendix G (federal regulatory provision)	161a
Appendix H (Oregon statutory provisions)	162a

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 02-35587

STATE OF OREGON, PLAINTIFF-APPELLEE

v.

JOHN ASHCROFT, ATTORNEY GENERAL, IN HIS OFFICIAL CAPACITY AS UNITED STATES ATTORNEY GENERAL; ASA HUTCHINSON, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION; KENNETH W. MAGEE, IN HIS OFFICIAL CAPACITY AS DIRECTOR OF THE DRUG ENFORCEMENT ADMINISTRATION, PORTLAND OFFICE; UNITED STATES OF AMERICA; UNITED STATES DEPARTMENT OF JUSTICE; UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS-APPELLANTS

v.

PETER A. RASMUSSEN; DAVID MALCOLM HOCHHALTER; RICHARD HOLMES; JAMES ROMNEY; MELISSA BUSH; JOHN DOE # 1, PLAINTIFFS-INTERVENORS-APPELLEES

Argued and Submitted May 7, 2003
Filed May 26, 2004

OPINION

Before: LAY,* WALLACE, and TALLMAN, Circuit Judges.

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* Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

TALLMAN, Circuit Judge.

A doctor, a pharmacist, several terminally ill patients, and the State of Oregon challenge an interpretive rule issued by Attorney General John Ashcroft which declares that physician assisted suicide violates the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. §§ 801-904. This so-called "Ashcroft Directive," published at 66 Fed. Reg. 56,607, criminalizes conduct specifically authorized by Oregon's Death With Dignity Act, Or. Rev. Stat. § 127.800-127.897. We hold that the Ashcroft Directive is unlawful and unenforceable because it violates the plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority. *See* 5 U.S.C. § 706(2)(C), (D). The petitions for review are granted.

I

We have original jurisdiction over "final determinations, findings, and conclusions of the Attorney General" made under the CSA. 21 U.S.C. § 877. Because the Attorney General maintains that his interpretive rule is a "final determination" and because the Directive orders sanctions for violations of its provisions, we have original jurisdiction pursuant to § 877. *See Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003) (holding that an interpretive rule issued by the Attorney General pursuant to the CSA is a "final determination" for jurisdictional purposes because the rule "impos[es] obligations and sanctions in the event of violation [of its provisions]"); *see also City of Auburn v. Qwest*, 260 F.3d 1160, 1171-73 (9th Cir. 2001). We consider the matter transferred to us from the district court pursuant to 28 U.S.C. § 1631.[1]

This case is ripe for review because, under the Directive, health care practitioners risk criminal prosecution and loss of the privilege to prescribe medication if they choose to assist in the suicide of terminally ill patients pursuant to Oregon's Death With Dignity Act. *See Hemp Indus.*, 333 F.3d at 1086 ("[I]f . . . the challenged regulations present[ ] plaintiffs with the immediate dilemma to choose between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation, the controversy is ripe.") (citation omitted). "Because standing overlaps substantially with ripeness" in these circumstances, the petitioner health care practitioners have standing to challenge the Ashcroft Directive. *See id.*[2]

---

[1] On April 17, 2002, United States District Judge Robert E. Jones entered a permanent injunction against enforcement of the Ashcroft Directive. 192 F. Supp. 2d 1077 (D. Or. 2002). Recognizing that he might lack jurisdiction over the matter, Judge Jones alternatively ordered the petitions for review transferred to us under 28 U.S.C. § 1631 ("Whenever a civil action is filed in a court . . . including a petition for review of administrative action . . . and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed [.]"). 192 F. Supp. 2d at 1086-87. Although we conclude that the district court did not have jurisdiction, Judge Jones' opinion on the merits is well reasoned, and we ultimately adopt many of his conclusions.

[2] We need not decide whether the other plaintiffs also have standing. *See Leonard v. Clark*, 12 F.3d 885, 888 (9th Cir. 1993). However, we do note the argument by the plaintiff patients that the Ashcroft Directive, if followed, will achieve the in terrorem effect intended. Doctors will be afraid to write prescriptions sufficient to painlessly hasten death. Pharmacists will fear filling

II

The Ashcroft Directive purports to interpret and implement the CSA, which Congress enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). The stated purpose of the CSA is "to provide increased research into, and prevention of, drug abuse and drug dependence . . . and to strengthen existing law enforcement authority in the field of drug abuse." *Id.* at 1236 (preamble); *see also* H.R. Rep. No. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567 ("This legislation is designed to deal in comprehensive fashion with the growing menace of drug abuse in the United States[.]"); *United States v. Moore*, 423 U.S. 122, 141, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975); *Raich v. Ashcroft*, 352 F.3d 1222, 1228-29 (9th Cir. 2003); *United States v. Rosenberg*, 515 F.2d 190, 194 (9th Cir. 1975) (noting that the purpose of the CSA is to "counter drug abuse").

Under the CSA, it is unlawful to prescribe or dispense controlled substances without a federal registration. 21 U.S.C. § 841(a)(1); *see also id.* §§ 823(f), 822(a)(2). The CSA originally provided automatic federal registration for state-licensed health-care practitioners. § 303(f), 84 Stat. at 1255. The Attorney General could revoke a practitioner's federal registration only if the practitioner falsified his or her registration application, was convicted of a felony related to

---

the prescriptions. Patients will be consigned to continued suffering and, according to the declarations of record, may die slow and agonizing deaths. Should patients attempt suicide without the assistance of their doctors and pharmacists, they may fail or leave loved ones with the trauma of dealing with the aftermath of certain forms of suicide too unpleasant to describe in this opinion.

a controlled substance, or had his or her state license suspended or revoked. *Id.* § 304(a), 84 Stat. at 1255.

In 1971, pursuant to his authority to issue rules regulating controlled substances under the CSA, *see* 21 U.S.C. § 871(b), then Attorney General John Mitchell promulgated the following regulation:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04 (originally designated as 21 C.F.R. § 306.04). This regulation exposed properly licensed and registered physicians to federal prosecution for distributing prescription drugs outside "the usual course of professional practice." *See, e.g., Moore*, 423 U.S. at 143, 96 S. Ct. 335 ("In practical effect, [Dr. Moore] acted as a large-scale 'pusher' not as a physician."); *Rosenberg*, 515 F.2d at 193 ("[A] doctor who acts other than in the course of professional practice is not a practitioner under the [CSA] and is therefore . . . . subject to the criminal provisions of the Act [.]") (citations omitted).

In 1984, Congress amended the CSA to give broader authority to the Attorney General. The Attorney General is now authorized to revoke a physician's pre-

scription privileges upon his determination that the physician has "committed such acts as would render his registration . . . inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). When determining which acts are inconsistent with the public interest, the Attorney General must consider the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority;
>
> (2) The applicant's expertise in dispensing . . . controlled substances;
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances;
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). Although this provision gives the Attorney General new discretion over the registration of health care practitioners, Congress explained that "the amendment would continue to give deference to the opinions of State licencing authorities, since their recommendations are the first of the factors to be considered[.]" S. Rep. No. 98-225, at 267 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449.

Against this backdrop of federal regulation, in 1994, the State of Oregon enacted by ballot measure the country's first law authorizing physician assisted suicide. *See* Or. Rev. Stat. § 127.800-897. Oregon's Death With Dignity Act authorizes physicians to prescribe lethal doses of controlled substances to terminally ill Oregon residents according to procedures designed to protect vulnerable patients and ensure that their decisions are reasoned and voluntary. *See id.*[3] Oregon voters reaffirmed their support for the Death With Dignity Act on November 4, 1997, by defeating a ballot measure that sought to repeal the law.

Soon thereafter, several members of Congress, including then Senator John Ashcroft, urged then-Attorney General Janet Reno to declare that physician assisted suicide violated the CSA. She declined to do so. In a letter dated January 5, 1998, Attorney General Reno explained that the CSA was not "intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice." She concluded that "the CSA does not authorize [the Drug Enforcement Administration ("DEA")][1] to prosecute, or to revoke DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law."[4]

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[3] Under Oregon's Death With Dignity Act, only adult Oregon residents suffering from an incurable disease likely to result in death within six months are eligible for a lethal prescription. Or. Rev. Stat. 127.800 § 1.01(12); *id.* 127.805 § 2.01(1). A patient's diagnosis must be confirmed by two independent physicians. *Id.* 127.815 § 3.01; 127.820 § 3.02. Patients must sign a written request for the prescription in the presence of two witnesses attesting that the patient is competent and acting voluntarily. *Id.* 127.810 § 2.02.

[4] In response to Attorney General Reno's letter, members of Congress introduced bills to amend the CSA to explicitly authorize the Attorney General to revoke the registration of any practitioner who "intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual." H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998"). The amendments

With a change of administrations came a change of perspectives. On November 9, 2001, newly appointed Attorney General John Ashcroft reversed the position of his predecessor and issued the Directive at issue here. The Ashcroft Directive proclaims that physician assisted suicide serves no "legitimate medical purpose" under 21 C.F.R. § 1306.04 and that specific conduct authorized by Oregon's Death With Dignity Act "may 'render [a practitioner's] registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation." 66 Fed. Reg. at 56,608 (quoting 21 U.S.C. § 824(a)(4)). The Directive specifically targets health care practitioners in Oregon and instructs the DEA to enforce this determination "regardless of whether state law authorizes or permits such conduct by practitioners." *Id.*[5]

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failed. In 1999, Congress again declined to enact a similar proposed amendment. *See* H.R. 2260, 106th Cong. (1999) ("Pain Relief Promotion Act of 1999").

[5] The dissent argues that the Ashcroft Directive does not ban physician assisted suicide outright, but only bars the use of controlled substances for assisting suicide. This argument is wrong for two reasons. First, the Attorney General may revoke physician prescription privileges for any conduct appropriately deemed inconsistent with the public interest; such conduct need not involve controlled substances. *See* 21 U.S.C. § 824(a)(4). Second, it is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives. *See* Gerrit K. Kimsma, *Euthanasia and Euthanizing Drugs in The Netherlands*, in DRUG USE IN ASSISTED SUICIDE AND EUTHANASIA 193, 198-204 (Margaret P. Battin and Arthur G. Lipman eds., 1996); Kathy Farber-Langendoen and Jason H.T. Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, ANNALS INTERNAL MED., Mar. 21, 2000, at 482-87.

III

To be perfectly clear, we take no position on the merits or morality of physician assisted suicide. We express no opinion on whether the practice is inconsistent with the public interest or constitutes illegitimate medical care. This case is simply about who gets to decide. All parties agree that the question before us is whether Congress authorized the Attorney General to determine that physician assisted suicide violates the CSA. We hold that the Attorney General lacked Congress' requisite authorization. The Ashcroft Directive violates the "clear statement" rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

A

We begin with instructions from the Supreme Court that the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide" belongs among state lawmakers. *Washington v. Glucksberg*, 521 U.S. 702, 735, 117 S. Ct. 2258 (1997). In *Glucksberg*, Justice O'Connor emphasized that "[s]tates are presently undertaking extensive and serious evaluation of physician-assisted suicide. . . . In such circumstances, the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance." *Id.* at 737, 117 S. Ct. 2258 (O'Connor, J., concurring) (citations and quotation marks omitted); *cf. Cruzan v. Director*, 497 U.S. 261, 293, 110 S. Ct. 2841, 111 L. Ed. 2d 224 (Scalia, J., concurring) ("[W]hen it *is* demonstrated . . . that a patient no longer wishes certain measures to be taken to preserve his or her life, it is up to the citizens[of the

States] to decide, through their elected representatives, whether that wish will be honored."). Here, Oregon voters have twice declared their support for the legalization of physician assisted suicide in their state. We disagree with the dissent's suggestion that this court, rather than the Attorney General, is interfering with the democratic process. *See Glucksberg*, 521 U.S. at 735, 117 S. Ct. 2258 ("Our holding permits this debate [about physician assisted suicide] to continue, as it should in a democratic society.").

The principle that state governments bear the primary responsibility for evaluating physician assisted suicide follows from our concept of federalism, which requires that state lawmakers, not the federal government, are "the primary regulators of professional [medical] conduct." *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002); *see also Glucksberg*, 521 U.S. at 737, 117 S. Ct. 2258 (O'Connor, J., concurring). The Supreme Court has made the constitutional principle clear: "Obviously, direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18, 45 S. Ct. 446, 69 L. Ed. 819 (1925); *see also Barsky v. Bd. of Regents*, 347 U.S. 442, 449, 74 S. Ct. 650, 98 L. Ed. 829 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power."). The Attorney General "may not . . . regulate [the doctor-patient] relationship to advance federal policy." *Conant*, 309 F.3d at 647 (Kozinski, J., concurring).[6]

[6] As noted in *Younger v. Harris*, 401 U.S. 37, 44-45, 91 S. Ct. 746, 27 L. Ed. 2d 669 (1971):

> The concept [of federalism] does not mean blind deference to "States' Rights" any more than it means centralization of control over every important issue in our National Government and its courts. The Framers rejected both these courses. What the concept does represent is a system in which there is sensitivity to the legitimate interests of both State and National Governments, and in which the National Government, anxious though it may be to vindicate and protect federal rights and federal interests, always endeavors to do so in ways that will not unduly interfere with the legitimate activities of the States.

By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders and therefore "alter[s] the 'usual constitutional balance between the States and the Federal Government.'" *Gregory v. Ashcroft*, 501 U.S. 452, 461, 111 S. Ct. 2395, 115 L. Ed. 2d 410 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242, 105 S. Ct. 3142, 87 L. Ed. 2d 171 (1985)). Under these circumstances, "[i]t is incumbent on the federal courts to be certain of Congress' intent" before finding that federal authority supercedes state law. *Gregory*, 501 U.S. at 460, 111 S. Ct. 2395 (quotation marks and citation omitted).

Unless Congress' authorization is "unmistakably clear," the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care. *Id.* at 460-61, 111 S. Ct. 2395 (quoting *Atascadero State Hosp.*, 473 U.S. at 242, 105 S. Ct. 3142); *see also Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173, 121 S. Ct. 675, 148 L. Ed. 2d 576 (2001) ("This concern is heightened where an administrative interpretation alters the federal-state

framework by permitting federal encroachment upon a traditional state power."); *United States v. Bass*, 404 U.S. 336, 349, 92 S. Ct. 515, 30 L. Ed. 2d 488 (1971) ("[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance."). In divining congressional intent, it is a "cardinal principle" of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, [federal courts shall] construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575, 108 S. Ct. 1392, 99 L. Ed. 2d 645 (1988).

The Ashcroft Directive is invalid because Congress has provided no indication—much less an "unmistakably clear" indication—that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide. By attempting to regulate physician assisted suicide, the Ashcroft Directive invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice. *See Linder*, 268 U.S. at 18, 45 S. Ct. 446; *Conant*, 309 F.3d at 639. Because Congress has not clearly authorized such an intrusion, the Ashcroft Directive violates the clear statement rule. *See Solid Waste Agency*, 531 U.S. at 172-73, 121 S. Ct. 675; *Yeskey*, 524 U.S. at 208-09, 118 S. Ct. 1952. We need not, and therefore do not, decide whether the Ashcroft Directive actually exceeds Commerce Clause boundaries, but only that it "invokes the outer limits of Congress' power" without explicit authority from Congress. *Solid Waste Agency*, 531 U.S. at 172, 121 S. Ct. 675 (citing *Edward J. DeBartolo*

Corp., 485 U.S. at 575, 108 S. Ct. 1392); *see also Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208-09, 118 S. Ct. 1952, 141 L. Ed. 2d 215 (1998) ("[A]bsent an unmistakably clear expression of intent to alter the usual constitutional balance between the States and the Federal Government, we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted).

B

The Ashcroft Directive not only lacks clear congressional authority, it also violates the plain language of the CSA. We hold that the Directive exceeds the scope of federal authority under the CSA, misconstrues the Attorney General's role under the statute, and fails to follow explicit instructions for revoking physician prescription privileges.

The CSA expressly limits federal authority under the Act to the "field of drug abuse." Pub. L. No. 91-513, 84 Stat. 1236; 21 U.S.C. § 801(2)-(6). Contrary to the Attorney General's characterization, physician assisted suicide is not a form of drug "abuse" that Congress intended the CSA to cover.[7]

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[7] The dissent argues that when Congress enacted the CSA it was not solely concerned with "drug abuse," as that term is commonly understood. The dissent suggests that a reference in the legislative record to "suicides and attempted suicides" and "drug-related deaths" indicates that Congress understood "drug abuse" to encompass physician assisted suicide. These excerpts are taken entirely out of context. In the record cited by the dissent, suicide is *distinguished* from "abuse," *see* H.R. Rep. No. 91-1444 (1970), 1970 U.S.C.C.A.N. at 4602, and statements concerning "drug-related deaths" clearly refer to overdoses from abuse of pharmaceutical drugs "diverted from the sick and injured to the black market." 130 Cong. Rec. 25,851 (1984) (statement of Rep. Rodino); 98 Cong.

Physician assisted suicide is an unrelated, general medical practice to be regulated by state lawmakers in the first instance. *Glucksberg*, 521 U.S. at 735, 737, 117 S. Ct. 2258 (O'Connor, J., concurring).

We know that Congress intended to limit federal authority under the CSA to the field of drug abuse because the statute's non-preemption clause provides that the CSA shall be not be construed to preempt state law unless there is a "positive conflict" between the text of the statute and state law. 21 U.S.C. § 903; *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 502, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001) (Stevens, J. concurring) ("[F]ederal courts [must], whenever possible, . . . avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a state have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country.") (citations and quotation marks omitted). No provision of the CSA directly conflicts with Oregon's Death with Dignity Act. However, the Attorney General's expansive interpretation of the CSA clearly conflicts with the Oregon law and therefore cannot be squared with the CSA's non-preemption clause. See 21 U.S.C. § 903; *see also Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325, 117 S. Ct. 832, 136 L. Ed. 2d 791 (1997) ("As is always the case in our pre-emption jurisprudence, where federal law is said to bar state action in fields of traditional state regulation, . . . we have worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (citation and quotation marks omitted).

Rec. 365 (1984) (statement of Rep. Waxman). The record is voluminous and replete with statements of congressional intent to combat drug abuse and addiction, and particularly the problem of doctors who illicitly funnel prescription drugs into the hands of dealers and addicts. Both the Attorney General and the dissent expand the scope of the CSA in a manner that contravenes and distorts Congress' will.

To the limited extent that the CSA does authorize federal regulation of medical practice, Congress carefully circumscribed the Attorney General's role. The Attorney General may not define the scope of legitimate medical practice. See Pub. Law No. 91-513, 84 Stat. at 1241 (now codified at 42 U.S.C. § 290bb-2a).[8] In *Moore*, the Supreme Court held that the CSA "requires" the Secretary of Health and Human Services "to determine the appropriate methods of professional practice" under the statute. 423 U.S. at 144, 96 S. Ct. 335 (quoting 42 U.S.C. § 290bb-2a); *see also Rosenberg*, 515 F.2d at 194-95.

The Attorney General, on the other hand, is authorized to revoke prescription privileges from physicians for conduct deemed "inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). However, in this case, the Attorney General improperly invokes this author-

[8] *See also* 21 U.S.C. § 811(b) ("The recommendations of the Secretary to the Attorney General [concerning which substances shall be covered by the CSA] shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug[.]"); 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in . . . regulations or practice guidelines [concerning the treatment of narcotic addicts] may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.").

ity. When determining what conduct is inconsistent with the public interest under the CSA, the Attorney General is required to consider five factors. *See* 21 U.S.C. § 823(f). The Attorney General reasons that physician assisted suicide is inconsistent with the public interest because the practice threatens public health. *See* Memorandum for the Attorney General from the Office of Legal Counsel, June 27, 2001 ("OLC Memo"), at 3-18.[9] Although threat to public health is one factor the Attorney General is to consider when determining the public interest, in this case he does not consider the other factors required by the statute. *See* 21 U.S.C. § 823(f).

The Attorney General misreads the CSA when he concludes that he may evaluate the public interest "based on *any* of the five factors identified in the statute." OLC Memo at 3 (emphasis added). The CSA clearly provides that all five public interest factors "*shall* be considered." 21 U.S.C. § 823(f) (emphasis added). When the Attorney General declares that his Directive shall apply "regardless of whether state law authorizes or permits such conduct," he ignores the very first factor he is required to consider under the Act—*i.e.* "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority." 21 U.S.C. § 823(f)(1). The Attorney General's categorical prohibition of physician assisted suicide also fails to consider the second and third public interest factors required under the CSA. *See* 21 U.S.C. § 823(f)(2), (3) (listing individual practitioner experience

[9] This memo is attached to the Ashcroft Directive and, according to the Attorney General, "sets forth the legal basis for my decision." 66 Fed. Reg. at 56,608.

and criminal history as the second and third public interest factors).

Thus, we see at least three conflicts between the Ashcroft Directive and the text of the CSA. First, the Directive purports to regulate medical practices outside the field of drug abuse and prevention, despite the statute's limited scope and Congress' stated intent. Second, the Directive makes a unilateral medical determination that may not be made by the Attorney General.[10] Finally, the Directive evaluates public interest under 21 U.S.C. § 823 without considering all five factors required by that subsection. *See* 5 U.S.C. § 706(2)(C), (D) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] without observance of procedure required by law[.]").

C

The CSA's legislative record confirms that the Attorney General has exceeded the scope of his authority. *See SEC v. McCarthy*, 322 F.3d 650, 655 (9th Cir. 2003) ("When the statute is ambiguous or the statutory language does not resolve an interpretive issue, our approach to statutory interpretation is to look to legislative history.") (citation and quotation marks omitted).

[10] We do not intend to imply that the Secretary of Health and Human Services may determine that physician assisted suicide constitutes an illegitimate medical practice. As noted, by its terms the CSA is limited to "the field of drug abuse," which is not so broad as to include conduct authorized by Oregon's Death With Dignity Act. See Pub. L. No. 91-513, 84 Stat. 1236 (preamble) (1970).

Congress clearly intended to limit the CSA to problems associated with drug abuse and addiction. *See, e.g.*, H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) ("[I]t cannot be overemphasized that the . . . [CSA] is designed to crackdown hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."). As we held in *Rosenberg*, "Congress was concerned with the diversion of drugs out of legitimate channels of distribution" when it enacted the CSA. 515 F.2d at 193. Congress acted to halt "'the widespread diversion of [controlled substances] out of legitimate channels into the illegal market'[.]" *Id.* at 194 (quoting H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4572).

Furthermore, recognizing that this mandate may at times encroach on a state's traditional authority to regulate medical practices, Congress empowered "the principal health agency of the federal government," not the Attorney General, to make medical decisions under the Act. *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4581 ("[T]he committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine. . . . In view of this situation, this section will provide guidelines, determined by the principal health agency of the federal government[.]"). In *Moore*, the Court observed that "Congress pointed out that criminal prosecutions *in the past* had turned on the opinions of federal prosecutors. Under the[CSA], those physicians who comply with the recommendations *made by the Secretary* [of Health and Human Services] will no longer jeopardize their professional careers[.]"

423 U.S. at 144, 96 S. Ct. 335. (emphasis added) (quotation marks and citation omitted).

In 1974, Congress amended the CSA to "cure the present difficulty in [resolving] . . . the intricate and nearly impossible burden of establishing what is beyond the 'course of professional practice' for criminal law purposes." *Moore*, 423 U.S. at 140, n. 16, 96 S. Ct. 335 (citation omitted). Although only tangentially related to this case, the 1974 amendment is noteworthy because it evinces Congress's intent to "preserve[ ] the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary [of Health and Human Services]. . . . *All decisions of a medical nature are to be made by the Secretary [of Health and Human Services].* Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General." H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034 (emphasis added).

Congress did not intend to expand the scope or general purpose of the CSA when it amended the statute in 1984 to give the Attorney General authority to revoke the federal registrations of physicians and pharmacists. *See* S. Rep. No. 98- 225 at 260, 261-62, 1984 U.S.C.C.A.N. at 3443-44 ("In particular, the amendments . . . are intended to address the severe problem of diversion of drugs of legitimate origin into the illicit market."). Nor did Congress intend to grant the Attorney General any broader authority than he already exercised over the registration of manufacturers and distributers of controlled substances. *See id.* at 3449 ("The broader considerations for registration of practitioners set out in[the amendments] . . . are

similar to those applicable under current law to registration applications on the part of manufacturers and distributors of controlled substances."). By enacting the 1984 amendments, Congress merely intended to close "loop-holes" in the original legislation by authorizing the Attorney General to revoke physician registrations without depending on state licencing boards, which had proven ineffective regulators of physicians who were diverting drugs into the illicit market. *See id.* at 3442- 44.

Finally, the legislative record demonstrates Congress' clear intent to prevent the Attorney General from revoking health care practitioners' DEA registrations on the sole basis of his decision that certain conduct "may threaten the public health and safety." *See* 21 U.S.C. § 823(f)(5). Congress unmistakably intended the Attorney General to consider all five factors under § 823(f) before determining whether physician conduct contravenes public interest. Congress specifically intended that the Attorney General must "continue to give deference to the opinions of the State licencing authorities," as their recommendations "are the first of the factors to be considered." S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449. It is undisputed that the Attorney General made no effort to solicit input from the State of Oregon before issuing his Directive, notwithstanding an express promise to do so by his subordinates within the United States Department of Justice.

D

The Ashcroft Directive proclaims that physician assisted suicide constitutes an illegitimate medical practice under 21 C.F.R. § 1306.04. Just as the Attorney

General's interpretation of the text of the CSA conflicts with the statute's plain language and the clear intent of Congress, so too does his interpretation of this regulation.

The Attorney General's interpretation of § 1306.04 exceeds the CSA's limited mandate to combat prescription drug abuse and addiction. *See* 21 U.S.C. § 801(2)-(6); Pub. L. No. 91-513, 84 Stat. 1236 (preamble); S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; *Rosenberg*, 515 F.2d at 193-95. To the extent that the federal regulation of controlled substances impacts medical care, the Supreme Court in *Moore* articulated no role for the Attorney General in determining the appropriate methods of medical practice under § 1306.04. *See* 423 U.S. at 144, 96 S. Ct. 335. While the 1984 amendments to the CSA do extend the Attorney General's authority over federal registration of practicing physicians, these changes neither impact § 1306.04 nor provide the Attorney General the authority to determine the scope of legitimate medical practice in the manner attempted here.

IV

Given the plain language of the CSA and its legislative record, we are under no obligation to defer to the Attorney General's interpretation of his role under the statute and its implementing regulations. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984); *see also Solid Waste Agency*, 531 U.S. at 172- 74, 121 S. Ct. 675. Agency determinations that squarely conflict with governing statutes are not entitled to deference. *Chevron*, 467 U.S. at 842-43, 104 S. Ct. 2778. We "must, of course,

set aside [agency] decisions which rest on an erroneous legal foundation." *NLRB v. Brown*, 380 U.S. 278, 291-92, 85 S. Ct. 980, 13 L. Ed. 2d 839 (1965) (citation and quotation marks omitted); *cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S. Ct. 1291, 146 L. Ed. 2d 121 (2000).

As already explained, the Ashcroft Directive exceeds the scope of the CSA and ignores the Attorney General's limited role. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble); *see also* S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44. The Attorney General fails to follow the CSA's clear instructions when he declares that his assessment of the public interest may be based on "any" of the five factors required under § 823(f) and that his determination shall apply "regardless of whether state law authorizes or permits such conduct." *See* 21 U.S.C. § 823(f); *see also* S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449.

We also note that the Attorney General has no specialized expertise in the field of medicine and that he imposes a sweeping and unpersuasive interpretation of the CSA—which directly conflicts with that of his predecessor—without notice or comment. There is no reason to defer to his interpretation of his authority under the CSA. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161, 89 L. Ed. 124 (1994) (holding that an agency's interpretation may merit some deference in a field of its specialized expertise); *see also United States v. Mead Corp.*, 533 U.S. 218, 234-35, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001).

Nor shall we defer to the Attorney General's interpretation of 21 C.F.R. § 1306.04, which conflicts with the Supreme Court's interpretation of the same regulation in *Moore*. *See* 423 U.S. at 144, 96 S. Ct. 335;

see also Alhambra Hosp. v. Thompson, 259 F.3d 1071, 1076 (9th Cir. 2001) (refusing to defer to an agency's interpretation of its own regulation when it conflicted with the "overriding intent" of Congress); *Maislin Indus., U.S., Inc. v. Primary Steel, Inc.*, 497 U.S. 116, 131, 110 S. Ct. 2759, 111 L. Ed. 2d 94 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

Citing federalism concerns, the Supreme Court recently refused to defer to an agency's interpretation of its own regulations without clear authority from Congress. *See Solid Waste Agency*, 531 U.S. at 172-74, 121 S. Ct. 675. As already explained, the Attorney General's interpretation of § 1306.04 permits him to override state regulation of general medical practices *despite* Congress' express intent to limit federal authority under the CSA to the field of drug abuse and addiction. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble); 21 U.S.C. § 801. Clearly, "our deference does not extend to agencies' constructions which conflict with statutory directives." *Pacific Coast Med. Enter. v. Harris*, 633 F.2d 123, 131 (9th Cir. 1980).[11]

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[11] The Supreme Court has also refused to extend deference to an agency's interpretation of a regulation when, as here, it conflicts with the agency's previous interpretation of the same regulation. *See Norfolk S. Railway Co. v. Shanklin*, 529 U.S. 344, 356, 120 S. Ct. 1467, 146 L. Ed. 2d 374 (2000) ("[N]o . . . deference is appropriate [because] [n]ot only is the [agency's] interpretation inconsistent with the text of [the regulation], but *it also contradicts the agency's own previous construction* [.]") (emphasis added); *Solid Waste Agency*, 531 U.S. at 168, 121 S. Ct. 675 (noting that the

V

In sum, the CSA was enacted to combat drug abuse. To the extent that it authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of Heath and Human Services, not to the Attorney General. The Attorney General's unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds the scope of his authority under federal law. We therefore hold that the Ashcroft Directive is invalid and may not be enforced.

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agency's new interpretation is unsupported by any "evidence that the [agency] mistook Congress' intent" the first time); see also *Pacific Coast Med. Enter.*, 633 F.2d at 131 ("The [regulation] must be reasonably susceptible to the construction placed upon them by the [agency], both on [its] face and in *light of [its] prior interpretation and application.*") (emphasis added). Nor is deference due when an agency's interpretation of a regulation conflicts with the agency's intent at the time the regulation was promulgated. *See Thomas Jefferson Univ. Hosp. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 129 L. Ed. 2d 405 (1994) (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430, 108 S. Ct. 1306, 99 L. Ed. 2d 515 (1988)). Here, the Attorney General asserts that the CSA and its implementing regulations must reflect a uniform federal standard of practice. But when Attorney General Mitchell promulgated 21 C.F.R. § 1306.04 in 1971, physicians were entitled to distribute controlled substances—as a matter of right—merely by complying with *state* law. *See* Pub. L. No. 91-513, 84 Stat. 1253, 1255 (§§ 303(f), 304(a)). Neither Congress nor Attorney General Mitchell could have intended § 1306.04 to empower the Attorney General to enforce a uniform federal standard of medical care, as contemplated here. when authorization to prescribe drugs under the CSA turned on the decisions of state licensing and law enforcement authorities. *See id.*

The petitions for review are GRANTED. The injunction previously entered by the district court is ORDERED continued in full force and effect as the injunction of this court.

WALLACE, Senior Circuit Judge, dissenting:

As my colleagues in the majority suggest, this case is not about the ethics or public policy implications of physician-assisted suicide. We need not decide whether the federal government or the states is better equipped to regulate physician-assisted suicide. Setting aside the public policy aspects of physician-assisted suicide that evoke passionate feelings, this case involves a single legal question: is the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) entitled to deference? Because our past decisions command deference to the Attorney General's interpretive rule, I would deny the petition for review on the merits.

I.

The Oregon Death with Dignity Act (Oregon Act) provides that a capable adult who "has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner." OR. REV. STAT. § 127.805(1). Once various safeguards have been satisfied, the attending physician may "writ[e] a prescription for medication to enable a qualified patient to end his or her life," *id.* § 127.815(1)(k), and the attending physician, the pharmacist, or a third person may dispense the medication to the patient, *id.* § 127.815(1)(L). To date,

Oregon is the only state that has passed legislation expressly legalizing physician-assisted suicide.

By authorizing physicians to prescribe and dispense controlled substances for the purpose of assisting suicide, the Oregon Act arguably draws Oregon law into tension with the federal Controlled Substances Act, 21 U.S.C. §§ 801-971. "Except as authorized by [the Controlled Substances Act]," it is unlawful for any person—including physicians—to "manufacture, distribute, or dispense" a controlled substance. 21 U.S.C. § 841. The Controlled Substances Act permits physicians to dispense controlled substances only if they have previously registered with the Attorney General. *Id.* §§ 822(a)(2), 823(f). Even registered physicians may not distribute controlled substances, however, without first issuing a "prescription," *id.* § 829(a), which, "to be effective[,] must be issued for a legitimate medical purpose," 21 C.F.R. § 1306.04(a). The Attorney General may revoke or suspend a physician's registration if the registrant has been convicted of violating the Controlled Substances Act, 21 U.S.C. § 824(a)(2), or has committed acts "inconsistent with the public interest," *id.* §§ 823(f), 824(a)(4).

Whether physician-assisted suicide is "a legitimate medical purpose" and "consistent with the public interest" has been the subject of considerable public debate. In a letter dated November 5, 1997, Drug Enforcement Administration (DEA) Administrator Thomas A. Constantine opined that assisting suicide is not a "legitimate medical purpose" under the Controlled Substances Act. Letter from Constantine, DEA Administrator, to Henry J. Hyde, Congressman (Nov. 5, 1997), available at http://www.house.gov/judiciary/constantine.htm. Seven months later, however, then-

Attorney General Janet Reno rejected the DEA Administrator's opinion letter, concluding that "the [Controlled Substances Act] does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Statement of Attorney General Reno on Oregon's Death with Dignity Act (June 5, 1998), *available at* http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html. General Reno's interpretation of the Controlled Substances Act prompted a stern letter from several Senators-including then Missouri Senator John Ashcroft:

> [T]here is agreement among all three branches of the Federal government that assisted suicide is not a legitimate medical practice. The DEA is therefore on solid ground in concluding that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose,'" and that such a misuse of drugs warrants the revocation of a physician's license to dispense controlled substances.

Letter from John Ashcroft et al., U.S. Senators, to Janet Reno, Attorney General (Dec. 19, 1997).

Following his appointment to head the Department of Justice, General Ashcroft issued an interpretive rule on November 9, 2001, reversing his predecessor's earlier position regarding physician-assisted suicide. Dispensing of Controlled Substances To Assist Suicide (Ashcroft Directive), 66 Fed. Reg. 56,607 (Nov. 9, 2001) (to be codified at 21 C.F.R. pt. 1306). The Ashcroft Directive states that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R.

§ 1306.04 (2001)" and that a physician who prescribes controlled substances to assist suicide "may' render his registration . . . inconsistent with the public interest'" and thereby risk suspension or revocation of his registration under 21 U.S.C. § 824(a)(4). *Id.* at 56,608. General Ashcroft directed "the DEA, effective upon publication of this memorandum in the Federal Register, to enforce and apply this determination, notwithstanding anything to the contrary in the June 5, 1998, Attorney General's letter." *Id.*

Before the Department of Justice took action to enforce the Ashcroft Directive, a group of physicians, patients, and the state of Oregon (collectively Petitioners) brought this action in federal district court, seeking declaratory and injunctive relief. Although the district court lacked jurisdiction to consider the petition for review, *see Pac. Power & Light Co. v. Bonneville Power Admin.*, 795 F.2d 810, 814-16 (9th Cir. 1986); *UMC Indus., Inc. v. Seaborg*, 439 F.2d 953, 955 (9th Cir. 1971) (per curiam), this court has jurisdiction pursuant to 28 U.S.C. § 1631 and 21 U.S.C. § 877.

II.

The Petitioners do not dispute that the Controlled Substances Act prohibits physicians from dispensing and prescribing controlled substances except for legitimate medical purposes. *See* 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose. . . ."); *United States v. Moore*, 423 U.S. 122, 124, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) (holding that physicians violate the Controlled Substances Act "when their activities fall outside the usual course of professional practice"); *United States v. Kaplan*, 895 F.2d 618, 619 (9th Cir.

1990) (stating that the Controlled Substances Act prohibits "prescribing controlled substances for reasons other than legitimate medical purposes"); *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975) (interpreting the Controlled Substances Act "to mean that a doctor who acts [outside] the course of professional practice is not a practitioner under the Act and is therefore not authorized to prescribe controlled substances"). Instead, they argue that the Ashcroft Directive is not a valid agency rule—and thus is not entitled to deference—for the following four reasons: (1) the Attorney General did not promulgate the Ashcroft Directive pursuant to the Administrative Procedure Act's (APA) notice-and-comment rulemaking procedures; (2) the Ashcroft Directive violates the Controlled Substances Act's non-preemption provision; (3) the Ashcroft Directive exceeds the scope of the Attorney General's authority under the Controlled Substances Act; and (4) the Ashcroft Directive is an arbitrary and capricious agency action. As will be seen, none of these creative challenges to the Ashcroft Directive withstands close scrutiny or justifies the majority's departure from our customary canons of deference to agency action.

A.

Petitioners argue first that deference to the Ashcroft Directive is not warranted because the Attorney General did not satisfy the APA's notice-and-comment rulemaking procedures. *See* 5 U.S.C. § 553 (requiring that agencies give "interested persons" notice of proposed rules and "an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation"). The United States counters that the

APA does not require notice and comment here, because the Ashcroft Directive is an interpretive rule, not a legislative rule. *See i d.* § 553(b)(3)(A) (stating the APA's notice-and-comment procedures do not ordinarily apply to interpretive rules). If the Ashcroft Directive is "genuinely an interpretive rule, it is valid despite the absence of notice and comment procedures." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003).

We distinguish interpretive and legislative rules by asking (1) whether, absent the rule, there would be an inadequate legislative basis for an enforcement action; (2) whether the agency "explicitly invoked its general legislative authority"; and (3) whether "the rule effectively amends a prior legislative rule." *Id.* "If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000), *quoting Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

The Ashcroft Directive does not bear any of these three hallmarks of a legislative rule. First, even absent the Ashcroft Directive, the Attorney General could bring an enforcement action because the Controlled Substances Act itself prohibits distributing a controlled substance without a prescription, 21 U.S.C. § 829(a), and preexisting Department of Justice regulations declare that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose," 21 C.F.R. § 1306.04(a). Second, the Attorney General did not expressly invoke his statutory authority to "promulgate . . . any [legislative rules] . . . which he may deem necessary and appropriate for the efficient execution of his functions under" the

Controlled Substances Act. 21 U.S.C. § 871(b). Third, although the Ashcroft Directive contradicts former Attorney General Reno's 1998 statement, the Ashcroft Directive is not inconsistent with any *legislative* rule. *See Chief Prob. Officers of Cal. v. Shalala*, 118 F.3d 1327, 1337 (9th Cir. 1997) (holding that an interpretive rule can amend an interpretive rule); Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 ADMIN. L. REV. 547, 566-73 (2000) (discussing this principle).

The Ashcroft Directive does not purport to "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp*, 333 F.3d at 1087. Instead, like other interpretive rules, the Ashcroft Directive is "essentially hortatory and instructional," clarifying what the Controlled Substances Act means when applied to a narrowly defined situation. *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984); *see also Hemp*, 333 F.3d at 1087 (explaining that interpretive rules "explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule"). Thus, General Ashcroft's failure to give Petitioners advance notice and an opportunity to comment does not invalidate the Ashcroft Directive.

B.

The Petitioners next contend that the Ashcroft Directive violates 21 U.S.C. § 903, the Controlled Substances Act's non-preemption clause. Section 903 reads:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates

> . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. The Petitioners argue that the Ashcroft Directive construes the Controlled Substances Act to preempt the Oregon Act and that this result violates 21 U.S.C. § 903 because there is no "positive conflict" between the Controlled Substances Act's text and the Oregon Act.

Petitioners are wrong; the Ashcroft Directive is consistent with section 903 because it does not utterly exclude state regulation of medical practice or even state regulation of physician-assisted suicide. The Ashcroft Directive does not effect a "positive conflict" with state law because it does not make "the federal role . . . so pervasive that no room is left for the states to supplement it." *Sayles Hydro Assocs. v. Maughan*, 985 F.2d 451, 455 (9th Cir. 1993). States may supplement the Ashcroft Directive by expanding the Controlled Substances Act's prohibitions, providing additional civil or criminal sanctions against physicians who assist suicide, or permitting conduct that the Ashcroft Directive does not prohibit.

More relevant for present purposes, the Ashcroft Directive proscribes only one method of assisting suicide: prescription, dispensation, and administration of controlled substances. The majority vastly exaggerates the Ashcroft Directive's scope by intimating that it "ban[s] physician-assisted suicide outright." A closer examination of the Ashcroft Directive's text reveals that "[assisting] suicide is not a 'legitimate medi-

cal purpose'" only "*within the meaning of 21 C.F.R. § 1306.04*" (prescription of controlled substances). Ashcroft Directive, 66 Fed. Reg. at 56,608 (emphasis added). The Ashcroft Directive avoids the sweeping prohibition claimed by the majority by assiduously limiting its reach to controlled substances; under its plain terms, only applications involving *controlled substances* may "render [a physician's] registration . . . inconsistent with the public interest" and therefore subject to revocation. *Id.*, *quoting* 21 U.S.C. § 824(a)(4). Oregon physicians may continue to assist suicide by other means without risking suspension or revocation of their registration to prescribe controlled substances. *See* George J. Annas, *The "Right To Die" in America: Sloganeering from* Quinlan *and* Cruzan *to* Quill *and* Kevorkian, 34 DUQ. L. REV. 875, 891 (1996) (discussing carbon monoxide as an alternative to controlled substances); Jeffrey G. Sherman, *Mercy Killing and the Right To Inherit*, 61 U. Cin. L. Rev. 803, 834 (1993) (same). The Ashcroft Directive does not, therefore, "occupy the field" of physician-assisted suicide in violation of section 903. *See United States v. Leal*, 75 F.3d 219, 227 (6th Cir. 1996) (holding that "there is no such conflict" between 21 C.F.R. § 1306.04 and state law).

C.

Petitioners maintain—and the majority agrees—that the Ashcroft Directive is not entitled to deference because the Attorney General promulgated it "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

1.

The Ashcroft Directive is not entitled to deference, the majority contends, because "Congress intended to

limit federal authority under the [Controlled Substances Act] to the field of drug abuse" while preserving states' discretion to authorize other life-threatening applications of controlled substances. By what authority? True, the Controlled Substances Act's preamble arguably manifests Congress's intent "to strengthen existing law enforcement authority in the field of drug abuse," Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, pmbl., 84 Stat. 1236, 1236, but it does not "expressly limit[ ] federal authority under the Act" to mainstream drug abuse, as the majority argues. Moreover, there is simply no textual support for the majority's conclusory assertion that "the field of drug abuse," as discussed in the Controlled Substances Act, does not encompass drug-induced, physician-assisted suicide.

The Controlled Substances Act's text furnishes ample evidence that Congress was concerned not only with street-variety drug trafficking and abuse but also with any other improper drug use that might have a "detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2). The Act targets all "improper use of controlled substances," *id.*, and gives the Attorney General discretion to decide whether registering a physician to dispense drugs is "consistent with the public health and safety," *id.* § 823(b)(5). Reasonable minds might disagree as to whether physician-assisted suicide constitutes an "improper use" of a controlled substance, but nothing in the Controlled Substances Act's text precludes its application to physician-assisted suicide.

Lacking a textual hook for its position, the majority attempts to patch the holes in its argument with inconclusive fragments of legislative history. Discern-

ing congressional intent from legislative history is a speculative enterprise under the best of circumstances, and the risk of error is compounded in a case such as this when legislators' published statements do not squarely address the question presented-i.e., whether Congress intended to exclude drug-induced, physician-assisted suicide from regulation under the Controlled Substances Act. *See Chisom v. Roemer*, 501 U.S. 380, 406, 111 S. Ct. 2354, 115 L. Ed. 2d 348 (1991) (Scalia, J., dissenting) ("We are here to apply the statute, not legislative history, and certainly not the absence of legislative history.").

The Controlled Substances Act's legislative history suggests that some members of Congress envisioned the physician-registration provisions primarily as a mechanism to stem the flow of controlled substances into illicit channels, *Moore*, 423 U.S. at 135, 96 S. Ct. 335, but the record also specifically identifies "suicides and attempted suicides" as a"[m]isuse of a drug." H.R. REP. NO. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572; *see also Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 Before the House Subcomm. on Health and the Env't*, 98th Cong. 365 (1984) (statement of Rep. Henry A. Waxman, Chairman, House Subcomm. on Health and the Env't) (expressing concern that "[d]rugs legally manufactured for use in medicine are responsible for a substantial majority of drug-related deaths"); 130 CONG. REC. 25,851 (statement of Rep. Rodino) (1984) (reporting that "diversion" of prescription drugs "is responsible for 70 percent of the deaths and injuries due to all drug abuse"). Viewed holistically, the record "does not demonstrate a clear and certain congressional intent" to preclude physician-assisted suicide from

regulation under sections 823 and 824. *Rust v. Sullivan*, 500 U.S. 173, 190, 111 S. Ct. 1759, 114 L. Ed. 2d 233 (1991). Controlling precedent thus compels the conclusion that the Controlled Substances Act's "legislative history . . . cannot form the basis for enjoining [the Attorney General's] regulation[ ]." *Id.*; *see also Student Loan Fund of Idaho, Inc. v. U.S. Dept. of Educ.*, 272 F.3d 1155, 1165 (9th Cir. 2001) (applying this principle in an analogous setting).

2.

The majority asserts that the Attorney General lacks authority to decide whether physician-assisted suicide is consistent with "the public interest" and a "legitimate medical practice" under the Controlled Substances Act and its implementing regulations because Congress intended to preserve the states' traditional authority to make these determinations. This argument ignores the Controlled Substances Act's text and controlling Supreme Court decisions.

It is axiomatic that the meaning of federal law is a federal question. *See Reconstr. Fin. Corp. v. Beaver County*, 328 U.S. 204, 208, 66 S. Ct. 992, 90 L. Ed. 1172 (1946) ("What meaning Congress intended is a federal question we must determine."). Although federal law occasionally incorporates state-law definitions by reference, *see, e.g.*, *De Sylva v. Ballentine*, 351 U.S. 570, 580-82, 76 S. Ct. 974, 100 L. Ed. 1415 (1956) (defining the word "children" in a federal statute according to state law), recourse to state law is the exception rather than the norm. "[I]n the absence of a plain indication to the contrary, . . . Congress when it enacts a statute [does] not mak[e] the application of the federal act dependent on state law." *Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43, 109 S. Ct. 1597, 104 L. Ed. 2d 29 (1989) (quoting *Jerome v. United States*, 318 U.S. 101, 104, 63 S. Ct. 483, 87 L. Ed. 640 (1943)); *Kahn v. INS*, 36 F.3d 1412, 1414 (9th Cir. 1994) (per curiam) (same).

State law may be *relevant* to certain provisions of the Controlled Substances Act, *see, e.g.*, 21 U.S.C. § 823(f) (instructing the Attorney General to consider state-law violations when deciding whether a physician's registration would be contrary to the public interest), but nothing in the Controlled Substances Act plainly evinces a congressional intent to define "the public interest" solely according to state law. On the contrary, section 823 instructs the Attorney General to identify acts "inconsistent with the public interest" by reference to a variety of sources, including a physician's federal conviction record, compliance with "Federal . . . laws relating to controlled substances," and "other conduct which may threaten public health and safety." *Id.* The majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band's* "plain indication" rule and contravenes Congress's clearly expressed intent.

The majority also cites *Washington v. Glucksberg*, 521 U.S. 702, 735, 737, 117 S. Ct. 2258, 138 L. Ed. 2d 772 (1997) (O'Connor, J., concurring), for the position that the Attorney General must defer to the Oregon Act because "[p]hysician-assisted suicide is an unrelated, general medical practice to be regulated by the States in the first instance." *Glucksberg*, however, addressed states' authority to *prohibit* physician-assisted suicide *in the absence of federal regulation*; the case did not answer the question whether Congress may exercise its

Commerce Clause power to deny physicians access to controlled substances for physician-assisted suicide. Rather than place federalism limitations on the federal government's authority to restrict physician-assisted suicide, Justice O'Connor's concurring opinion stressed that "[t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill . . . individuals . . . and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Id.* at 737, 117 S. Ct. 2258. Simply put, courts should defer to the political process instead of interposing hasty constitutional constraints.

Glucksberg does not require the Attorney General to interpret the Controlled Substances Act and its implementing regulations according to state standards of professional conduct. Rather, the Supreme Court's decision stands for the broader proposition that federal courts generally should keep their distance, allowing the political process to decide whether and how to regulate physician-assisted suicide. The majority's shortsighted decision to declare the Ashcroft Directive invalid has precisely the opposite effect.

3.

As an alternative, the majority contends that the Secretary of Health and Human Services (Secretary)—not the Attorney General—should decide whether medical practices are "legitimate" and consistent with the "public interest" under the Controlled Substances Act and its implementing regulations. The Controlled Substances Act's text directly contradicts this argument: "*The Attorney General* may deny an application for . . . registration [of a practitioner to dispense

drugs] if *he determines* that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f) (emphasis added). Congress could not have stated more plainly that the Attorney General, not the Secretary, has authority to determine whether a physician's registration is consistent with the public interest.

The majority's reading of section 823 is a particularly astonishing exercise in statutory construction because the Controlled Substances Act specifically provides for the Secretary's participation in other discretionary judgments. *See, e.g.*, 21 U.S.C. § 811(b) (providing that the Secretary's determination with respect to the classification of controlled substances "shall be binding on the Attorney General"); *id.* § 823(f) (authorizing the Secretary to evaluate a practitioner's "qualifications and competency" to perform "research with controlled substances"); *id.* (stating that the Secretary "shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of . . . controlled substances from legitimate medical or scientific use"); *id.* § 823(g)(2)(H)(i) (empowering the Secretary to "issue regulations . . . or issue practice guidelines" for the approval of "additional credentialing bodies"). When Congress wished to entrust a discretionary judgment to the Secretary it said so explicitly. The Controlled Substances Act conspicuously omits any reference to the Secretary, however, when discussing the Attorney General's authority to assess "the public interest" for purposes of ordinary physician registrations. *Id.* § 823(f). The explanation for this omission is perfectly clear: section 823 authorizes the Attorney General—not the Secretary—to decide whether a

physician's registration is consistent with the public interest.

The majority asserts that under the Controlled Substance Act all standards of legitimate professional conduct are set by the Secretary, not by the Attorney General. The majority's argument relies on a section of the Act entitled "Medical Treatment of Narcotic Addiction," which is located in a different title of the legislation. This section provides that the Secretary, "after consultation with the Attorney General . . ., shall determine the appropriate methods of professional practice in the medical treatment of . . . *narcotic addiction*." 42 U.S.C. § 290bb 2a (emphasis added). Obviously, this is irrelevant to the issue before us. Yet from this narrow provision, the majority draws the sweeping, untenable conclusion that the Attorney General cannot enforce the Controlled Substances Act against a physician unless the Secretary first concludes that the prescription did not issue for a "legitimate medical purpose."

The Supreme Court rejected a similar challenge to the Attorney General's interpretive authority in *Moore*. The Court explained that Congress designed subsection 290bb 2a to function only as a limited safe-harbor for physicians who prescribe controlled substances to drug addicts; as long as physicians employ the treatment methods outlined in the Secretary's published standards of professional practice, the Attorney General may not prosecute them under the Controlled Substances Act. *Moore*, 423 U.S. at 144, 96 S. Ct. 335. The Court recognized, however, that "[t]he negative implication [of this provision] is that physicians who go beyond approved practice remain subject to serious criminal penalties." *Id.* In other words, section 290bb-

2a prevents the Attorney General from enforcing the Controlled Substances Act and its implementing regulations only when the Secretary declares that a specific *narcotic addiction treatment* serves a "legitimate medical purpose."

We confirmed *Moore's* reading of subsection 290bb 2a in *Rosenberg*, holding that the Attorney General may enforce the Controlled Substances Act against physicians whose practices do not qualify for protection under the Secretary's specific safe-harbor guidelines. We explained that the Secretary's authority to

> determine the appropriate method of professional practice in the medical treatment of narcotic addiction . . . was adopted in light of Congress' awareness that there had been criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors. *The committee evidenced no intention to restrict such prosecutions.* Indeed[,] *they seemed to think [these prosecutions] would continue*, but that some standards of professional practice should be established so that . . . physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers by accepting narcotic addicts as patients.

515 F.2d at 194-95 (emphasis added) (internal quotations omitted), *citing* H.R. REP. NO. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. at 4581 (observing that "for the last 50 years" federal officials have "determine[d] the appropriate method of the practice of medicine . . . through . . . criminal prosecution[s]" and suggesting that these prosecutions should continue subject to the Secretary's limited guidelines for treatment of narcotic

addiction); *see also* H.R. REP. NO. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034 (recognizing that "[t]he registration required under [the section of the Controlled Substances governing treatment of narcotic addiction] is *separate and distinct* from regular registration under the Controlled Substances Act," which is administered by the Attorney General (emphasis added)).

Here the Petitioners have not shown and do not contend that the Secretary's guidelines approve physician-assisted suicide as an "appropriate method[ ] of professional practice in the medical treatment of . . . *narcotic addiction*." 42 U.S.C. § 290bb 2a (emphasis added). As such, subsection 290bb 2a's safe-harbor rule does not apply, and the Attorney General was not required to consult the Secretary prior to issuing his determination that physician-assisted suicide does not constitute a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a).

4.

The majority maintains that even if the Controlled Substances Act authorizes the Attorney General to ascertain whether physician-assisted suicide is "inconsistent with the public interest," General Ashcroft abused his discretion in this case by failing to consider all five factors outlined in 21 U.S.C. § 823(f). Subsection (f) provides in part that "[i]n determining the public interest, the following factors shall be considered":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

28 U.S.C. § 823(f). The Ashcroft Directive is invalid, the majority argues, because General Ashcroft "made no effort to solicit input from the State of Oregon before issuing" the interpretive rule.

Contrary to the majority's assertion, the Ashcroft Directive does not sidestep subsection 823(f)'s five-factor inquiry. The Justice Department has yet to initiate an enforcement action against any individual physician pursuant to section 824, so the hour has not arrived for the Attorney General to consider subsections 823(f)(1)-(4) (i.e., the state licensing board's recommendation and physicians' relevant experience and criminal record). The Ashcroft Directive merely cautions that a physician who prescribes controlled substances to assist suicide "*may* 'render his registration . . . inconsistent with the public interest,'" Ashcroft Directive, 66 Fed. Reg. at 56,608 (emphasis added); it does not declare that assisting suicide *shall* render a physician's registration inconsistent with the public interest. This word choice is significant, because it conclusively refutes the majority's contention that assisting suicide *automatically* renders a physician's registration "inconsistent with the public interest"

under the Ashcroft Directive. Even if "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," the Attorney General remains free to consult all of section 823's five factors—including the recommendation of Oregon's licensing board or disciplinary authority—before making a final decision whether to suspend or revoke a particular physician's registration.

Significantly, the Ashcroft Directive's warning that assisting suicide could prompt Controlled Substances Act enforcement actions comports with fundamental administrative law principles:

> When a governmental official is given the power to make discretionary decisions under a broad statutory standard [e.g., "the public interest"], case-by-case decisionmaking may not be the best way to assure fairness. Here the [Attorney General] . . . sought to define the statutory standard . . . by the use of his rulemaking authority. The decision to use objective rules in this case provides [physicians] with more precise notice of what conduct will be sanctioned and promotes equality of treatment among similarly situated [individuals].

Dixon v. Love, 431 U.S. 105, 115, 97 S. Ct. 1723, 52 L. Ed. 2d 172 (1977). The Controlled Substances Act facilitates adherence to these principles by expressly authorizing the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871. Thus, General Ashcroft acted well within the scope of his statutory authority in declaring that assisting suicide does not serve a "legitimate medical

purpose" under 21 C.F.R. § 1306.04(a) and that this practice "may 'render [a physician's] registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation under [section] 824." Ashcroft Directive, 66 Fed. Reg. at 56,608.

5.

Finally, the majority argues that the Ashcroft Directive exceeds the Attorney General's statutory authority because Congress has not clearly authorized the Attorney General to upset the delicate balance between federal regulation of controlled substances and state control of medical practices. As support for this conclusion, the majority invokes the Supreme Court's recent analysis in *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 121 S. Ct. 675, 148 L. Ed. 2d 576 (2001):

> Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. This requirement stems from our prudential desire not to needlessly reach constitutional issues and our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority. This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.

Id. at 172-73, 121 S. Ct. 675 (internal citations omitted), *citing Edward J. DeBartalo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575, 108 S. Ct. 1392, 99 L. Ed. 2d 645 (1988). *See generally id.* at

172-74, 108 S. Ct. 1392 (refusing to afford deference to an agency regulation that raised a serious constitutional issue where there was no indication in the statute that Congress intended to encroach on traditional state powers over land and water use). Although the Court addressed the validity of "an administrative interpretation of a *statute*," *id.* at 172, 121 S. Ct. 675 (emphasis added), its reasoning should apply equally to an administrative interpretation of an agency regulation.

Solid Waste's clear statement rule is based upon understandable and significant federalism concerns, the importance of which I do not doubt. The question we must ask ourselves, however, is whether this canon of statutory interpretation applies to the case before us.

Not every colorable constitutional question triggers *Solid Waste's* clear statement rule. Our past decisions dictate that we must "scrutinize constitutional objections to[the] agency interpretation skeptically. Only if the agency's proffered interpretation raises *serious* constitutional concerns may [we] refuse to defer. . . ." *Williams v. Babbitt*, 115 F.3d 657, 662 (9th Cir. 1997), *citing Republican Nat'l Comm. v. Fed. Election Comm'n*, 76 F.3d 400, 409 (D.C. Cir. 1996). As such, the proper approach here is to proceed directly to the merits of Petitioners' constitutional challenge, deciding whether the agency interpretation "raise[s] the sort of grave and doubtful constitutional questions" that could lead us to "invalidate the regulations in order to save the statute from unconstitutionality." *Rust*, 500 U.S. at 191, 111 S. Ct. 1759 (internal quotation marks omitted); *see also United States v. Deaton*, 332 F.3d 698, 704-08 (4th Cir. 2003) (construing the *Solid Waste* canon in light of *Rust* and deciding the disputed constitutional question to determine if it is serious enough to warrant

requiring a clear statement). Only if the Attorney General's proposed interpretation would likely render the statute unconstitutional do we apply *Solid Waste's* clear statement canon. *See Williams*, 115 F.3d at 663 ("*Rust* . . . limits this intrusion on agency power to situations where it's absolutely necessary."). Applying these principles, we should not require a clear statement in this case because controlling precedent compels the conclusion that the Attorney General's interpretation did not invoke "the outer limits" of Congress's Commerce Clause power. *Solid Waste*, 531 U.S. at 172, 121 S. Ct. 675; *see also Republican Nat'l Comm.*, 76 F.3d at 409 ("Because we can easily resolve the [constitutional] challenges through the application of controlling precedent . . ., we do not face the sort of serious constitutional questions 'that would lead us to assume Congress did not intend to authorize the [regulation's] issuance.'" (quoting *Rust*, 500 U.S. at 191, 111 S. Ct. 1759)).

The Commerce Clause empowers Congress to regulate (1) "the use of the channels of interstate commerce"; (2) "the instrumentalities of interstate commerce, or persons or things in interstate commerce"; and (3) "those activities that substantially affect interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-59, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995). Our court has long recognized that "the Commerce Clause empowers the federal government to regulate prescription drugs," *In re Grand Jury Proceedings*, 801 F.2d 1164, 1169 (9th Cir. 1986) (per curiam); accord *Rosenberg*, 515 F.2d at 198. We have steadfastly upheld the Controlled Substances Act against Commerce Clause challenges, even in cases involving wholly intrastate activity. *See, e.g., United States v. Tisor*, 96 F.3d 370,

375 (9th Cir. 1996); *United States v. Kim*, 94 F.3d 1247, 1250 (9th Cir. 1996). *But see Raich v. Ashcroft*, 352 F.3d 1222, 1227-28 (9th Cir. 2003) (stating that the Controlled Substances Act, as applied to "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to a valid California state law," likely exceeded Congress's Commerce Clause power).

Turning to the specific issue raised here—whether the prescription or dispensation of controlled substances to assist suicide substantially affects interstate commerce—we base our assessment on four factors:

> 1) whether the statute in question regulates commerce or any sort of economic enterprise; 2) whether the statute contains any express jurisdictional element which might limit its reach to a discrete set of cases; 3) whether the statute or its legislative history contains express congressional findings that the regulated activity affects interstate commerce; and 4) whether the link between the regulated activity and a substantial effect on interstate commerce is attenuated.

United States v. McCoy, 323 F.3d 1114, 1119 (9th Cir. 2003) (internal quotation marks omitted). Of these four factors, the first and last are most important. *Id.*

The Ashcroft Directive clearly satisfies *McCoy's* first and the last criteria. The Ashcroft Directive regulates economic transactions: physicians generally prescribe and dispense controlled substances for a fee. There is no indication here, as there was in *Raich* with regards to medicinal marijuana, that drug-induced physician-

assisted suicide "does not involve [the] sale, exchange, or distribution" of controlled substances. *Raich*, 352 F.3d at 1229. The link between these transactions and their effect on interstate commerce is not attenuated simply because relatively few Oregonians use controlled substances for assisted suicide. We evaluate whether an activity's link to interstate commerce is attenuated by assessing whether its effect on interstate commerce is sufficiently *direct*, *Solid Waste*, 531 U.S. at 195, 121 S. Ct. 675; *McCoy*, 323 F.3d at 1123-24, and we assess individual provisions as "part[s] of a wider regulatory scheme" (i.e., the Controlled Substances Act), which regulates a field of drug-related activity that has "a 'substantial affect' on interstate commerce," *Tisor*, 96 F.3d at 375. Here Congress naturally and directly reduces the amount of a controlled substance that flows through the interstate channels when it prohibits the substance's distribution for a particular use. Thus, the link between drug prescriptions and interstate commerce is sufficiently direct and substantial even if the drugs ultimately are used in intrastate activities such as physician-assisted suicide and the activities' disaggregated effect on interstate commerce is small.

Because the Ashcroft Directive satisfies *McCoy's* first and last factors, we need not consider whether it meets the other, less important ones. See *McCoy*, 323 F.3d at 1119 (explaining that the second and third factors may "aid" the court's analysis, but "are ordinarily not, in themselves, dispositive"); *id.* at 1126-27 (observing that legislative history is "neither necessary nor conclusive" in Commerce Clause analysis). Under *McCoy*, Congress' Commerce Clause power to prohibit physicians from prescribing controlled substances to

assist suicide is not open to serious question. That ends the matter in this circuit and, of course, for this case.

The majority cannot have it otherwise. Their argument that "*direct* control of medical practice in the states is beyond the power of the federal government" misses the point. *Linder v. United States*, 268 U.S. 5, 18, 45 S. Ct. 446, 69 L. Ed. 819 (1925) (emphasis added). Unless and until the Supreme Court directs us differently, our opinions and other binding precedent compel the conclusion that Congress acts comfortably within its Commerce Clause power when it regulates the prescription and dispensation of controlled substances. *See Minor v. United States*, 396 U.S. 87, 98 n. 13, 90 S. Ct. 284, 24 L. Ed. 2d 283 (1969) (stating that "a flat ban on certain [drug transactions] . . . is sustainable under the powers granted Congress" by the Commerce Clause); *Reina v. United States*, 364 U.S. 507, 511, 81 S. Ct. 260, 5 L. Ed. 2d 249 (1960) (referring to Congress's "undoubted power to enact the narcotics laws"); *Tisor*, 96 F.3d at 375 ("[D]rug trafficking is a commercial activity which substantially affects interstate commerce."); *Kim*, 94 F.3d at 1250 n. 4 (recognizing that Congress may regulate controlled substances pursuant to the Commerce Clause even when legislation "intrudes into an area traditionally regulated by states"); *Rosenberg*, 515 F.2d at 198 (dubbing an analogous constitutional challenge "singularly unpersuasive"). General Ashcroft's interpretation of 21 C.F.R. § 1306.04(a) does not, therefore, "invoke[ ] the outer limits of Congress' power," *Solid Waste*, 531 U.S. at 172, 121 S. Ct. 675, the clear statement rule does not apply, and we must evaluate the Ashcroft Directive according to ordinary standards of deference.

D.

The Petitioners contend that the Ashcroft Directive constitutes an arbitrary and capricious interpretation of section 1306.04(a)'s "legitimate medical practice" requirement. General Ashcroft's determination is arbitrary and capricious, they argue, because he failed to examine the "wealth" of substantive data documenting the Oregon Act's effect on public health and safety. They point to a collection of studies which indicate that the Oregon Act's procedures have not been used disproportionately by the poor, uneducated, or uninsured. "Normally, an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983).

Although these empirical studies might be socially important, their findings were not an "important aspect of the problem" confronted by the Attorney General. General Ashcroft had before him a single question: whether physician-assisted suicide is a "legitimate medical purpose" as defined in existing case law, federal policy, general state law, and medical opinion. Evidence that Oregon physicians used the Oregon Act's procedures disproportionally against the poor, uneducated, or uninsured could have strengthened his conclusion that physician-assisted suicide is not a "legitimate medical purpose," but it does not follow that the absence of such evidence means physician-assisted suicide is a "legitimate medical practice." Thus, whether the Oregon Act provided adequate safeguards for vulnerable groups was not a sufficiently important aspect of the Attorney General's inquiry to render the

Ashcroft Directive an arbitrary and capricious agency action.

Furthermore, Petitioners' assertion that General Ashcroft "entirely failed to consider" Oregon's position on the social benefits of physician-assisted suicide is plainly false. The Attorney General based his decision on a memorandum from the Office of Legal Counsel, which considered, but rejected, Oregon's position in favor of existing case law, federal policies and practices, the majority state position, and the dominant views of the American medical and nursing professions. *See* Memorandum from Shelden Bradshaw, Deputy Assistant Attorney General, and Robert J. Delahunty, Special Counsel, *Memorandum for the Attorney General: Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under the Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act* (Memorandum) 5-14 (June 27, 2001). Thus, Petitioners have not shown that General Ashcroft's decision to reject the Oregon Act's permissive approach to physician-assisted suicide was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(a).

III.

Having demonstrated the fallacies of the foregoing challenges to the Ashcroft Directive, I now consider what standard of review this court should apply when assessing the Ashcroft Directive's validity. The degree of deference we accord an interpretive rule depends upon whether the rule construes a statute or an agency regulation.

If the Ashcroft Directive represents a statutory interpretation, it enjoys deference as defined in *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 (1944). *Omohundro v. United States*, 300 F.3d 1065, 1067-68 (9th Cir. 2002). Under *Skidmore*, "[t]he weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140, 65 S. Ct. 161. Especially relevant under *Skidmore* is the fact that the Ashcroft Directive reverses the agency's earlier interpretation. *See Cmty. Hosp. of the Monterey Peninsula v. Thompson*, 323 F.3d 782, 792 (9th Cir. 2003) ("An agency interpretation . . . which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view." (internal brackets, quotation marks, and citation omitted)). The agency "is not disqualified from changing its mind," however, "and when it does, the courts still sit in review of the administrative decision and should not approach the statutory construction issue *de novo* and without regard to the administrative understanding of the statutes." *NLRB v. Local Union No. 103, Int'l Ass'n of Bridge, Structural & Ornamental Iron Workers*, 434 U.S. 335, 351, 98 S. Ct. 651, 54 L. Ed. 2d 586 (1978).

If the Ashcroft Directive interprets an agency regulation, rather than the Controlled Substances Act itself, we must accord it "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 129 L. Ed. 2d 405 (1994). Under this highly deferential standard,

> [o]ur task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation. In other words, we must defer to the Secretary's interpretation unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation.

Id. (internal citations and quotation marks omitted). Agency interpretations of regulations enjoy substantial deference even if they are inconsistent with the agency's prior interpretations. As the Supreme Court explained in *Thomas Jefferson*, an agency "is not estopped from changing a view[it] believes to have been grounded upon a mistaken legal interpretation." *Id.* at 517, 114 S. Ct. 2381 (internal quotation marks and citation omitted). "[W]here the agency's interpretation of [its regulation] is at least as plausible as competing ones, there is little, if any, reason not to defer to its construction." *Id.* (internal quotation marks and citation omitted) (second brackets in original).

In my view, the Ashcroft Directive constitutes an interpretation of a regulation rather than a statutory interpretation. The Ashcroft Directive's single interpretive act is to "determine that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)." Ashcroft Directive, 66 Fed. Reg. at 56,608. The Petitioners point to General Ashcroft's warning that prescribing a controlled substance to assist suicide may render a physician's registration subject to suspension or revocation under section 824(a)(4). This statement was not an *interpretation* of

the Controlled Substances Act, however, but an explanation of the logical consequences flowing from General Ashcroft's interpretation of 21 C.F.R. § 1306.04. If assisting suicide is not a "legitimate medical purpose," the direct result is that a physician cannot prescribe controlled substances for this purpose without violating Controlled Substances Act section 829 and thereby risking suspension or revocation of their registration under sections 823 and 824. *See* 21 U.S.C. § 823(f)(4) (stating that a physician's violation of federal law is relevant to determine if his registration is inconsistent with the public interest); *id.* § 824(a)(4) (providing that a physician's registration may be revoked for acts inconsistent with the public interest under section 823). Petitioners' contention that General Ashcroft was interpreting the word "practitioner" under 21 U.S.C. § 829 is likewise wrong. Nothing in the Ashcroft Directive turns upon the definition of "practitioner." Thus, the Ashcroft Directive qualifies for *Thomas Jefferson's* highly deferential standard of review.

Applying the *Thomas Jefferson* standard, I have no trouble upholding the Ashcroft Directive from Petitioners' attack. As the Office of Legal Counsel concluded:

> [T]he overwhelming weight of authority in judicial decisions, the past and present policies of nearly all of the States and of the Federal Government, and the clear, firm and unequivocal views of the leading associations within the American medical and nursing professions, establish that assisting in suicide is not an activity undertaken in the course of professional medical practice and is not a legitimate medical purpose. Indeed, we think it fair to say that

> physician-assisted suicide should not be considered a *medical* procedure at all. . . . It is plainly a fallacy to assume that a procedure must be "medical" because it is performed by a physician rather than, say, by a family member, or because it involves the use of a drug that a physician has prescribed.

Memorandum at 13-14; *see also* Ashcroft Directive, 66 Fed. Reg. at 56,608 (stating that the Memorandum "sets forth the legal basis for my decision"). In *Glucksberg*, the Supreme Court offered a similar assessment: "opposition to and condemnation of suicide—and, therefore, of assisting suicide—are consistent and enduring themes of our philosophical, legal, and cultural heritages. More specifically, for over 700 years, the Anglo American common-law tradition has punished or otherwise disapproved of both suicide and assisting suicide." *Glucksberg*, 521 U.S. at 711, 117 S. Ct. 2258 (internal citations omitted). Given this overwhelming historical, legal, and medical consensus that physician-assisted suicide is not a legitimate medical purpose, the Ashcroft Directive clearly satisfies *Thomas Jefferson*. Therefore, I would defer to the Ashcroft Directive's conclusion that physician-assisted suicide is not a "legitimate medical practice" under 21 C.F.R. § 1306.04(a).

IV.

Although I concur with the majority's brief discussion on justiciability and its conclusion as to our jurisdiction, I write separately to address the latter, as it is contested by the parties and resolved improperly by the district court, yet given scant attention by the majority. The majority suggests that *Hemp Industries Association v. DEA*, 333 F.3d 1082 (9th Cir. 2003), is

dispositive, but *Hemp Industries* declined to answer the precise question at issue here; that is, we left open "whether we would have original jurisdiction over an interpretive rule." *Id.* at 1085. A more thorough analysis is therefore needed to determine whether the Ashcroft Directive, which by its terms is an interpretive rule, is a "final determination" within the meaning of 21 U.S.C. § 877 over which we would have jurisdiction.

Section 877 provides that "[a]ll final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved." 21 U.S.C. § 871. The section provides us original jurisdiction where "any person aggrieved by a final decision of the Attorney General" seeks "review of the decision." *Id.* Significantly, the Ashcroft Directive echoes the language of this provision by "advis[ing] . . . that the original DEA *determination* is reinstated and should be implemented." Ashcroft Directive, 66 Fed. Reg. 56,608 (emphasis added); *see also, e.g., id.* ("I hereby *determine* that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001). . . ." (emphasis added)); *id.* ("I hereby direct the DEA . . . to enforce and apply this *determination*. . . ." (emphasis added)). Although helpful, the Attorney General's choice of words does not necessarily mean his "determination" is "final."

The district court held that the Ashcroft Directive is not "final" because General Ashcroft kept his own counsel, gave no notice or opportunity for comment, took no evidence, and did not produce an administrative record. As the district court observed, there is a paucity of appellate court decisions analyzing section

877's requirements for review. In order to respond to the district court's argument, therefore, I must reason by analogy and look to general principles of administrative law formulated under the APA. *See U.S. West Communications, Inc. v. Hamilton*, 224 F.3d 1049, 1054-55 (9th Cir. 2000) (using the APA's definition of "final" to interpret "final orders" under the Hobbs Act). For an agency action to be final under the APA, the agency need not obtain outside advice. It need not give notice and an opportunity to comment. *Guadamuz v. Bowen*, 859 F.2d 762, 771 (9th Cir. 1988). Absent a contrary command under the governing statute, the agency need not produce an administrative record, especially for review of purely legal questions such as those in the case before us.

As the Supreme Court held in *Bennett v. Spear*, 520 U.S. 154, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997), an agency action is "final" under the APA if it satisfies two criteria: (1) "the action must mark the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature"; and (2) "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 177-78, 117 S. Ct. 1154 (internal citations and quotation marks omitted). In evaluating whether an agency action meets these conditions, relevant considerations include: (a) whether the action is a "definitive statement of an agency's position," (b) whether it has a "direct and immediate effect on the complaining parties," (c) whether it "has the status of law," and (d) whether it "requires immediate compliance." *Assn. of Am. Med. Colls. v. United States*, 217 F.3d 770, 780 (9th Cir. 2000).

As an interpretive rule, the Ashcroft Directive does not have the "force of law." *Hemp Indus. Ass'n*, 333 F.3d at 1087. Nevertheless, this does not necessarily preclude the Ashcroft Directive from constituting a "final determination." In *Abbott Laboratories v. Gardner*, 387 U.S. 136, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967), *overruled on other grounds, Califano v. Sanders*, 430 U.S. 99, 97 S. Ct. 980, 51 L. Ed. 2d 192 (1977), the Supreme Court announced that finality is to be interpreted "in a pragmatic way," meaning that even pre-enforcement regulations that merely state an agency's intentions may be final for review. *Id.* at 149-50, 87 S. Ct. 1507; *see also Alaska v. EPA*, 244 F.3d 748, 750 (9th Cir. 2001) (order) (holding that the EPA's pre-enforcement order to invalidate a permit was final). Because an interpretive rule can be a final order, and because "final orders" are analytically equivalent to "final agency actions," *U.S. West Communications*, 224 F.3d at 1055, it follows that interpretive rules can constitute final agency actions under the APA. Thus, the Ashcroft Directive may qualify as a final agency action notwithstanding the fact that it has not been enforced and does not have the force of law.

Turning to the first *Bennett* requirement, the Ashcroft Directive clearly marks the consummation of the Attorney General's decision making process even though it is a nonbinding, pre-enforcement, interpretive rule. The Ashcroft Directive reflects internal agency deliberation, on a matter of public importance, and commands immediate implementation. Eschewing tentative or equivocal words, it speaks in the immediate and imperative language of final agency action. *See* Ashcroft Directive, 66 Fed. Reg. at 56,608 ("I hereby direct the DEA . . . to enforce and apply this

determination. . . ."); *accord Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 702 (D.C. Cir. 1971) (holding that "when [an agency's] interpretation is not labeled as tentative or otherwise qualified by arrangement for reconsideration" there is "no basis" for concluding that the "'agency action' is 'not final' for purposes of the APA and judicial review"). The Ashcroft Directive purports to be the Attorney General's interpretation, not the interpretation of an underling whose view may be overruled. *Accord Nat'l Automatic Laundry*, 443 F.2d at 701 (reasoning that "with the authoritative interpretative ruling by the [agency head,] the agency's interpretative action has come to an end, and there is no fair basis for saying this process will be disrupted by judicial review"). In addition, the Attorney General's decision to publish the Ashcroft Directive in the Federal Register, rather than simply issue a press release or send an opinion letter to a private party, indicates that the Ashcroft Directive represents the consummation of his decision-making process. For these reasons, the Ashcroft Directive clearly satisfies the first *Bennett* inquiry.

The next question under *Bennett* is whether legal consequences flow from the agency action. 520 U.S. at 178, 117 S. Ct. 1154. Relevant factors include whether the agency action has a "direct and immediate effect" on the complaining parties and requires their "immediate compliance." *Am. Med. Colls.*, 217 F.3d at 780. As explained previously, an interpretive rule may be a final agency action even though it is not legally binding.

The Ashcroft Directive satisfies this second requirement as well. Although it may not have the force of law, the Ashcroft Directive significantly and immedi-

ately alters the legal landscape for Oregon physicians. *See Bennett*, 520 U.S. at 178, 117 S. Ct. 1154 (holding that an agency action met this requirement because it had similar "direct and appreciable legal consequences"); *Abbott Labs.*, 387 U.S. at 152-53, 87 S. Ct. 1507 (holding that where plaintiffs must either comply with unfavorable regulations immediately or "risk serious criminal and civil penalties," the agency action satisfies this requirement). The Ashcroft Directive "direct[s] the DEA, effective upon publication of this memorandum in the Federal Register, to enforce and apply" the Attorney General's interpretation of 21 C.F.R. § 1306.04(a). This instruction created direct and immediate consequences for physicians who wish to prescribe controlled substances for assisted suicide.

It is of no moment that physicians will not experience the Ashcroft Directive's concrete legal effects unless they actually choose to prescribe controlled substances for assisted suicide. An agency action can be final even if its concrete legal effects are contingent upon a future event. *City of Fremont v. FERC*, 336 F.3d 910, 914 (9th Cir. 2003) (concluding that agency orders that attach legal consequences to future proceedings are final for judicial review). The Ashcroft Directive requires the physicians' immediate compliance. Thus, it satisfies *Bennett's* second requirement for finality.

Because the Ashcroft Directive constitutes a final agency action under *Bennett*, the instant petition for review falls squarely within this court's original jurisdiction. I therefore concur in the majority's assessment that the district court was without jurisdiction and the petition should be considered transferred to this court under 28 U.S.C. § 1631.

V.

Although I am convinced of the merits of my legal argument, I admit that even if I persuaded one of my colleagues to join me, my opinion would not be a final chapter. Those who are uneasy with my position (as I assume Petitioners will be) should see its limited grasp. The Ashcroft Directive constitutes a final agency action, but it surely will not be the last word on physician-assisted suicide. The Ashcroft Directive does not spell the end of the public's "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," *Glucksberg*, 521 U.S. at 735, 117 S. Ct. 2258, nor does it halt states' "extensive and serious evaluation of physician-assisted suicide and other related issues," *Glucksberg*, 521 U.S. at 736, 737, 117 S. Ct. 2258 (O'Connor, J., concurring). State legislators may supplement the Ashcroft Directive's sanctions, and they may authorize alternative methods for assisting suicide that do not involve the prescription of controlled substances.

More to my point, the Ashcroft Directive is not even an immutable expression of *federal* policy. A change in presidential administrations or a shift in the current President or Attorney General's perspective might precipitate the Ashcroft Directive's rescission. Certainly, Congress is free to enact legislation limiting or counteracting the Ashcroft Directive's effects. Although opinions differ over the propriety of assisted suicide, I fully subscribe to Justice O'Connor's canny observation that there is simply "no reason to think that the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the [government]'s interests in protecting

those who might seek to end life mistakenly or under pressure." *Id.* In short, we should trust the democratic process.

Thus, the discrete question before this court is a narrow one: is the Attorney General's interpretation of 21 C.F.R. § 1306.04 entitled to deference? Nothing in the Controlled Substances Act's text or legislative history authorizes the majority to deny deference to the Ashcroft Directive. As an interpretive rule, the Ashcroft Directive is not subject to the APA's notice-and-comment rulemaking procedures. It does not violate the Controlled Substances Act's nonpreemption provision. It neither exceeds the Attorney General's statutory authority under the Controlled Substances Act nor "push[es] the limit of congressional authority" under the Commerce Clause. *Solid Waste*, 531 U.S. at 173, 121 S. Ct. 675. Petitioners have not demonstrated that the Ashcroft Directive's interpretation of section 1306.04 is arbitrary and capricious. For these reasons, firmly established principles of administrative law formulated by the Supreme Court and our court command us to defer to the Attorney General's interpretation of section 1306.04.

Therefore, I dissent.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

No. 01-1647-JO

STATE OF OREGON, PLAINTIFF

AND

PETER A. RASMUSSEN; ET AL.,
PLAINTIFF-INTERVENORS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS UNITED STATES ATTORNEY GENERAL; ASA HUTCHINSON, IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION; KENNETH W. MAGEE, IN HIS OFFICIAL CAPACITY AS DIRECTOR OF THE DRUG ENFORCEMENT ADMINISTRATION, PORTLAND OFFICE; UNITED STATES OF AMERICA; UNITED STATES DEPARTMENT OF JUSTICE; AND UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS-APPELLANTS

April 17, 2002

OPINION AND ORDER

Before: ROBERT E. JONES, District Judge.

INTRODUCTION

After surviving voter and legal challenges, the 1994 Oregon Death with Dignity Act ("Oregon Act"), O.R.S. 127.800 *et seq*, finally went into effect in October 1997.

On November 6, 2001, with no advance warning to Oregon representatives, Attorney General John Ashcroft (herein referred to as "Ashcroft") fired the first shot in the battle between the state of Oregon and the federal government over which government has the ultimate authority to decide what constitutes the legitimate practice of medicine, at least when schedule II substances regulated under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*, are involved. Ashcroft began the battle by issuing the so-called "Ashcroft directive,"—a few paragraphs published in the Federal Register on November 9, 2001, in which Ashcroft declares, in relevant part, that

- controlled substances may not be dispensed to assist suicide, thus reversing the position taken by his predecessor, Attorney General Janet Reno, in June 1998.

- assisting suicide is not a "legitimate medical purpose" and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.

- prescribing, dispensing, or administering federally controlled substances to assist suicide may "render [a physician's] registration * * * inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4).

66 FR 56608 (Nov. 9, 2001).

Through his directive, Ashcroft evidently sought to stifle an ongoing "earnest and profound debate" in the various states concerning physician-assisted suicide.

Washington v. Glucksberg, 521 U.S. 702, 735, 117 S. Ct. 2258, 138 L. Ed. 2d 772 (1997). In *Glucksberg*, the Supreme Court was called upon to decide whether the state of Washington's statutory ban on assisted suicide violated the Due Process Clause. In a thoughtful opinion, the Court acknowledged that "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality and practicality of physician-assisted suicide." The Court recounted the various states' "serious, thoughtful examinations" of the issues in this difficult debate, including Oregon's 1994 enactment of the Oregon Act. *See* 521 U.S. at 716-19, 117 S. Ct. 2258. The Court declined to "strike down the considered policy choice" of the State of Washington, deferring instead to that state's resolution of the debate. 521 U.S. at 719, 724, 735, 117 S. Ct. 2258.

In her concurring opinion in *Glucksberg*, Justice O'Connor further elaborated that

> [t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure. * * * States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. * * * In such circumstances, "the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance."

Glucksberg, 521 U.S. at 737, 117 S. Ct. 2258 (O'Connor, J., concurring) (citations omitted).

As the Court acknowledged in *Glucksberg*, the citizens of Oregon, through their democratic initiative process, have chosen to resolve the moral, legal, and ethical debate on physician-assisted suicide for themselves by voting—not once, but twice—in favor of the Oregon Act. The Oregon Act attempts to resolve this "earnest and profound debate" by "strik[ing] the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Glucksberg*, 521 U.S. at 737, 117 S. Ct. 2258 (O'Connor, J., concurring).

With publication of the Ashcroft directive, Ashcroft essentially nullified the Oregon Act and four years of Oregon experience in implementing it. In response to what it perceived as an unwarranted and unauthorized intrusion into the sovereign interests of Oregon, the medical practices of Oregon physicians, and the end-of-life decisions made by terminally-ill Oregonians, plaintiff state of Oregon ("plaintiff") immediately commenced this lawsuit to, among other things, enjoin Ashcroft and the other defendants[1] from giving the Ashcroft directive any legal effect. A temporary

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[1] The defendants are John Ashcroft, Asa Hutchinson in his official capacity as Administrator of the Drug Enforcement Agency ("DEA"), Kenneth Magee in his official capacity as Director of the DEA in Portland, Oregon, the United States, the United States Department of Justice, and the DEA.

restraining order, issued on November 8, 2001, remains in effect.[2]

Despite the enormity of the debate over physician-assisted suicide, the issues in this case are legal ones and, as pertain to my disposition, are fairly narrowly drawn. My resolution of the legal issues does not require any delving into the complex religious, moral, ethical, medical, emotional or psychological controversies that surround physician-assisted suicide or "hastened death" (as the parties sometimes describe it), because in Oregon, those controversies have been—for now—put to rest.

The case presently is before me on several motions: (1) plaintiff's motion for summary judgment (# 111); (2) intervenors' motions for summary judgment or partial summary judgment (## 85, 101); and (3) defendants' motion to dismiss and alternative motion for summary judgment (# 133). For the reasons stated below, I grant plaintiff's and intervenors' motions for summary judgment in part and today enter a permanent injunction enjoining defendants from enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive at issue in this case. Those portions of plaintiff's and intervenors' motions not addressed in this opinion are denied as moot.[3] Defendants' motion to dismiss and alternative motion for summary judgment are denied.

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[2] The procedural history of this case is discussed more fully below.

[3] The patient intervenors also filed a motion for class certification (# 41). During the hearing on March 22, 2002, defendants agreed not to object to the addition or substitution of new patient plaintiffs as needed to continue the viability of patient-plaintiffs' claims in this action. Patient-plaintiffs remain concerned, however, so I have included in the injunction language prohibiting defendants from objecting to additions or substitutions of patients during the pendency of this case. In view of defendants' agreement and the injunction, the motion for class certification is denied.

FACTUAL AND PROCEDURAL BACKGROUND

1. *The Controlled Substances Act*

Congress enacted the CSA, 21 U.S.C. §§ 801-950, as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides a comprehensive federal scheme for regulation and control of certain drugs and other substances. The congressional findings supporting Title II reveal that Congress' overarching concern in enacting the CSA was the problem of drug abuse and illegal trafficking in drugs. *See* 21 U.S.C. § 801.

The CSA establishes five schedules of controlled substances, ranging from schedule I substances, which have no accepted medical use and can be utilized only in very limited contexts, to schedules II, III, IV, and V substances, which have recognized uses and can be manufactured, distributed, possessed and used, subject to the restrictions of the CSA. *See* 21 U.S.C. §§ 812, 841. The CSA sets forth initial schedules, 21 U.S.C. § 812(c), and specifies procedures by which the Attorney General may add, remove, or transfer substances to or between schedules. 21 U.S.C. § 811.

The CSA makes it unlawful for any person to manufacture, distribute, or dispense any controlled substance "[e]xcept as authorized by [the CSA]." 21 U.S.C. § 841(a)(1). As pertinent in this case, physicians who prescribe controlled substances and pharmacists who fill the prescriptions are considered "practitioners" who

"dispense" controlled substances. 21 U.S.C. § 802(10) and (21). To obtain authorization to do so, practitioners must register with the Attorney General and obtain a Drug Enforcement Agency ("DEA") certificate of registration. 21 U.S.C. § 822.

Under the CSA as originally enacted, state-licensed practitioners were entitled to be registered with the DEA as a matter of right. *See* 21 U.S.C. § 823(f)(1983) ("Practitioners shall be registered to dispense * * * controlled substances in schedule II, III, IV, or V if they are authorized to dispense * * * under the law of the State in which they practice"); *see also United States v. Moore*, 423 U.S. 122, 140-41, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) (registration mandatory if applicant authorized under state law). The Attorney General could suspend or revoke a practitioner's registration only if the registrant (1) materially falsified an application; (2) was convicted of a felony relating to controlled substances; or (3) had his or her state license or registration suspended or revoked. *See* 21 U.S.C. § 824(a) (1983).

Congress has amended the CSA many times since 1970. *See* Oregon's Memorandum in Support of Motion for Summary Judgment, p. 4 n. 22 (amendments cited). With each amendment, Congress further attempted to address the problems of drug abuse and illegal trafficking in drugs. In 1984, apparently concerned with the domestic diversion of otherwise legitimate medical controlled substances into the illegal market by registered practitioners, Congress again amended the CSA. As pertinent here, the 1984 amendment empowered the Attorney General to deny, suspend, or revoke a practitioner's DEA registration if the Attorney General "determines that the issuance of such registration

would be inconsistent with the public interest." 21 U.S.C. § 823(f); *see also* 21 U.S.C. § 824(1)(4).

In 1971, under authority delegated by the Attorney General pursuant to 21 U.S.C. § 871(a), the predecessor to the Administrator of the DEA[4] adopted formal regulations implementing the CSA. One of the regulations, now codified at 21 C.F.R. § 1306.04, provides, in relevant part:

> A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the usual course of his professional practice. * * * An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a)(emphasis added).

2. *The Oregon Death with Dignity Act*

In November 1994, Oregon voters enacted the Oregon Act through the initiative process. Having survived legal challenges, *see Lee v. State of Or.*, 891 F. Supp. 1429 (D. Or. 1995) (Oregon Act does not provide sufficient safeguards for terminally ill persons and therefore violates the Equal Protection Clause), *va-*

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[4] The predecessor agency was the Bureau of Narcotics and Dangerous Drugs.

cated 107 F.3d 1382 (9th Cir. 1997), and an initiative that would have repealed it, the Oregon Act went into effect in October 1997.

The Oregon Act provides a detailed procedure by which a mentally competent, terminally ill patient may make a written request for medication "for the purpose of ending his or her life in a humane and dignified manner * * *." O.R.S. 127.805(1). Once a valid request has been properly documented and all waiting periods have expired, the attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. Physicians and pharmacists are immune from civil and criminal liability and any adverse disciplinary action for participating in good faith compliance with the Oregon Act. *See generally* O.R.S. 127.805-.885; *see also* Affidavit of Stephen Bushong ("Bushong Aff."), Exh. 5, pp. 1-2.

Since 1997, the Oregon Act has been utilized by approximately 70 terminally ill Oregonians. Although defendants quibble somewhat with the data,[5] the parties appear to agree that these patients all utilized medications that are listed as schedule II controlled substances under the CSA.

3. *Events Giving Rise to This Action*

On July 27, 1997, Senator Orrin Hatch and Representative Henry Hyde sent a letter to the Administrator of the DEA advocating an interpretation of the CSA that would, in effect, permit the DEA to revoke the

[5] Defendants state that they have not been provided data from which they can verify whether controlled substances were utilized by all patients. *See* Defts.' Response to Plaintiff State of Oregon's Concise Statement of Material Facts, ¶ 2.

registrations of physicians and pharmacists who take actions authorized by the Oregon Act. *See* Bushong Aff., Exh. 1. In late October 1997, Hatch and Hyde sent a second letter to the DEA, expressing "heightened * * * urgency" resulting from the United States Supreme Court's decision to deny certiorari in *Lee v. State of Or.*, *supra*, which had, until then, kept the Oregon Act from going into effect. Bushong Aff., Exhibit 2. The second letter included a memorandum that purported to provide a legal basis for a proposed interpretation of the CSA that would make it illegal to prescribe controlled substances for the purpose of assisted suicide. Bushong Aff., Exh. 2, pp. 4-7.

On November 5, 1997, then-DEA Administrator Thomas Constantine wrote Hyde a letter in which he expressed the opinion that

> delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a "legitimate medical purpose." As a result, the activities that you described in you[r] letter to us would be, in our opinion, a violation of the CSA.
>
> * * *
>
> DEA must examine the facts on a case-by-case basis to determine whether a physician's actions conflict with the CSA. If the facts indicate that a physician has acted as set forth in your letter, however, then DEA would have a statutory basis to initiate revocation proceedings.

Bushong Aff., Exh. 3.

By letter dated December 3, 1997, Oregon Deputy Attorney General David Schuman, Ph.D., J.D., a noted constitutional scholar and former Professor of Law, University of Oregon, wrote to Jonathan Schwartz of the United States Department of Justice ("USDOJ") urging USDOJ to reconsider the DEA's position. Bushong Aff., Exh. 4. After considering Oregon's response and making her own evaluation, on June 5, 1998, then-Attorney General Janet Reno responded to Hyde's "request concerning the question whether the Department of Justice, through the [DEA], may invoke the [CSA] * * * to take adverse action against any physicians who assist patients in ending their lives by prescribing controlled substances." Bushong Aff., Exh. 5. Reno stated that the USDOJ "has reviewed the issue thoroughly" and has concluded that "the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA." Bushong Aff., Exh. 5, pp. 1, 4. USDOJ's opinion was confirmed by letter to Oregon Attorney General Hardy Myers the same day. *See* Bushong Aff., Exh. 6.

Between 1998 and 2000, two separate federal legislative attempts to preempt the Oregon Act failed to pass.[6] On February 2, 2001, Hardy Myers wrote to newly-appointed Attorney General John Ashcroft asking that "[i]f the current interpretation of the CSA in relation to [the Oregon Act] is to be reexamined,"

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[6] The Lethal Drug Abuse and Prevention Act of 1998, which was introduced in Congress in 1998 and which would have preempted the Oregon Act, failed to reach the floor of either the House or the Senate. The Pain Relief Promotion Act of 1999 passed the House in 1999, but failed to reach the Senate floor for a vote. *See* Bushong Aff., ¶ 8.

Oregon representatives be given an opportunity to meet with USDOJ representatives to discuss the issue. Bushong Aff., Exh. 7. Two months later, on April 17, 2001, a representative of USDOJ wrote Myers on behalf of Ashcroft, stating that

> I am aware of no pending legislation in Congress that would prompt a review of the Department's interpretation of the CSA as it relates to physician-assisted suicide. *Should such a review be commenced in the future, we would be happy to include your views in that review.*

Bushong Aff., Exh. 8 (emphasis added).

On June 27, 2001, two USDOJ attorneys, Sheldon Bradshaw and Robert Delahunty, sent a "Memorandum for the Attorney General" that reexamined, in great detail, the then-existing USDOJ interpretation of the CSA in relation to the Oregon Act. Bushong Aff., Exh. 9. Notwithstanding the assurances made on Ashcroft's behalf in April 2001, that "we would be happy to include [Oregon's] views in that review," the 24-page memorandum evidently was researched and written without any request for or consideration of Oregon data or comments of Oregon representatives. The memorandum was not disclosed to Oregon Attorney General Myers until November 6, 2001. Bushong Aff., ¶ 10. Thus, the Attorney General of the United States completely ignored his earlier promise to the Oregon Attorney General to ascertain Oregon's views. In doing so, he lost the opportunity to evaluate carefully the scientifically conducted epidemiological studies of the Oregon Act, and the excellent analysis of the multiple issues as set forth in the briefs submitted by plaintiff and intervenors in these proceedings.

On November 6, 2001, Ashcroft issued a memorandum to DEA Administrator Asa Hutchinson. This memorandum, the so-called "Ashcroft directive," relies on the June 27, 2001, Bradshaw/Delahunty memorandum as "the legal basis for my [Ashcroft's] decision." Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, Exhibit 1, p. 1. The Ashcroft directive reinstates the "original DEA determination," and directs the DEA to "enforce and apply this determination" upon publication in the Federal Register. *Id.* at p. 2. Significantly for purposes of the present proceeding, the Ashcroft directive states:

> I hereby determine that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. § 1306.04 (2001), and that the prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.

Id. at p. 1.

The Ashcroft directive was published in the Federal Register on November 9, 2001. *See* Bushong Aff., Exhibit 10. Before publication, defendants did not consult with Oregon public officials, provide any notice to them or to the Oregon general public, or provide any opportunity for any public comment anywhere.

PROCEDURAL BACKGROUND

On November 7, 2001, plaintiff state of Oregon commenced this action by filing a complaint for declaratory and injunctive relief together with a motion for a temporary restraining order ("TRO") or a preliminary injunction to enjoin defendants from enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive pending further order of the court. Following

a hearing on November 8, 2001, I granted plaintiff's motion and entered a TRO. I also granted motions to intervene filed by Peter Rasmussen, M.D., and David Hochhalter, Rph, and by certain terminally-ill patients[7] (together, the "intervenors").

On November 20, 2001, I held a full hearing on plaintiff's and intervenors' motions for preliminary injunction. Following the hearing, I continued the TRO and established a briefing schedule for the parties' dispositive motions. In mid-January 2002, a second group of patients sought and were granted leave to intervene.

On March 22, 2002, I held a full hearing on the merits of the pending motions. Following the hearing, I took the motions under advisement. I have reviewed and thoroughly considered the parties' arguments and submissions, as well as the submissions of the numerous amici curiae.[8]

As I suggested to the parties during the March hearing, the resolution of this case turns on the CSA and does not require constitutional analysis. As did former Attorney General Reno almost four years ago, I conclude that Congress did not intend the CSA to override

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[7] Although I granted the individual patients' motion to intervene, I denied intervenor status to the organization, Compassion in Dying of Oregon.

[8] Amici curiae briefs have been filed on behalf of the following: New York Physicians, ACLU Foundation of Oregon, Inc., Association of the Bar of the City of New York, Surviving Family Members, Autonomy, Inc., et al, American Academy of Pain Management, et al, Coalition of Mental Health Professionals, Not Dead Yet, et al, National Right to Life Committee and Oregon Right to Life, and the Family Research Council. The court thanks all amici for their valuable and insightful submissions.

a state's decisions concerning what constitutes legitimate medical practice, at least in the absence of an express federal law prohibiting that practice. Similarly, I conclude that Congress never intended, through the CSA or through any other current federal law, to grant blanket authority to the Attorney General or the DEA to define, as a matter of federal policy, what constitutes the legitimate practice of medicine.

Moreover, while I tend to agree with plaintiff and intervenors that the Ashcroft directive fails to pass muster as a matter of administrative law,[9] I decline to resolve this case on that basis. Whether characterized as a substantive or an interpretative rule, the fact remains that the Ashcroft directive exceeds the authority delegated to the defendants under the CSA.

DISCUSSION

I. *Defendants' Motion to Dismiss*

For the first time in this proceeding, defendants challenge this court's subject matter jurisdiction over plaintiff's and intervenors' claims. Defendants maintain that under 21 U.S.C. § 877, exclusive jurisdiction to review the Ashcroft directive rests with the courts of appeals. Section 877 provides:

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[9] The Ashcroft directive bears little similarity to another alleged "interpretive rule" recently issued under the CSA. That rule, which was brought to the court's attention as supplemental authority by defendants, serves to underscore how hastily the Ashcroft directive appears to have been crafted and published. *See* Notice of Filing Supplemental Authority in Support of Defendants' Motion to Dismiss (Order in *Hemp Industries Associationl v. DEA*, No. 01-71662 (9th Cir. March 7, 2002)); *see also* 66 FR 51530, 51535, and 51539 (Oct. 9, 2001).

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within 30 days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

According to defendants, the Ashcroft directive is a "final determination" within the meaning of that provision.

There is little pertinent authority to inform my decision on this issue. Two matters, however, are certain. First, defendants do not contend and could not maintain any argument that plaintiff did not initiate this action within 30 days after notice of Ashcroft's decision. *See* Transcript of Proceedings ("TR") (March 22, 2002), pp. 51-52.[10] Second, although in their motion, defendants insist that this action must be dismissed, they now agree that if this court should decide that section 877 divests jurisdiction, transfer to the Ninth

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[10] *See Nutt v. Drug Enforcement Admin.*, 916 F.2d 202, 204 n. 2 (5th Cir. 1990) (district court could cure jurisdictional defect caused by petitioner's failure to timely file petition for review of agency decision in court of appeals by transferring the petition pursuant to 28 U.S.C. § 1631).

Circuit Court of Appeals pursuant to 28 U.S.C. § 1631 would be appropriate.[11] *Id.* at p. 50.

After careful consideration of this question, I conclude that the Ashcroft directive, however it is characterized, is not a final determination, finding, or conclusion within the meaning of section 877. Although the correct answer to this question is by no means clear, in the balance I am persuaded that section 877 applies in situations where the Attorney General makes a quasi-judicial determination that resolves disputed facts in a specific case after some level of administrative proceedings; for example, in classifying a substance under section 811, or in denying, suspending, or revoking a DEA registration under sections 823 or 824, and the like. *See, e.g., Humphreys v. Drug Enforcement Admin.*, 96 F.3d 658 (3rd Cir. 1996) (appellate court review of DEA revocation of physician's registration); *Nutt v. Drug Enforcement Admin.*, 916 F.2d 202 (5th Cir. 1990) (appellate court had jurisdiction to review DEA revocation of physician's registration). Section 877 may also, at least theoretically, apply where the Attorney General undertakes formal rulemaking, which

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[11] 28 U.S.C. § 1631 provides:

> Whenever a civil action is filed in a court * * * or an appeal, including a petition for review of administrative action, is noticed for or filed with such a court and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed, and the action or appeal shall proceed as if it had been filed in or noticed for the court to which it is transferred on the date upon which it was actually filed in or noticed for the court from which it is transferred.

he did not do in this case.[12] Those types of proceedings "under this subchapter" produce administrative records susceptible to review by an appellate court.

In this present case, in contrast, the Attorney General essentially kept his own counsel, did not provide notice or an opportunity for comment, did not take any vidence, did not decide disputed facts, and more importantly, did not produce an administrative record. Instead, the only record with respect to the Ashcroft directive is the one currently being created in this court.

Moreover, even defendants appear to concede that section 877 is not exclusive, recognizing that "plaintiffs can obtain district court review only one way, by demonstrating that the review provision is inapplicable to their particular claim." Memorandum in Support of Defendants' Motion ("Defendants' Memorandum"), p. 10. In *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 111 S. Ct. 888, 112 L. Ed. 2d 1005 (1991), the Supreme Court examined an Immigration and Nationality Act provision that, similar to section 877, provided for only a single level of review in the courts of appeals. In ruling that the district court retained jurisdiction to

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[12] In this regard, I acknowledge defendants' submission of supplemental authority, *Hemp Industries Association v. DEA*, No. 01- 71662 (9th Cir.), which consists of a Ninth Circuit order staying operation of a DEA "Interpretive Rule" pending a hearing of the appeal on the merits. There is nothing before this court to suggest that the issues in that case and this one are in any respect similar. Moreover, defendants have themselves raised in *Hemp* the question of whether a DEA interpretive rule is subject to review under section 877. *See* Oregon Response to Notice of Filing of Supplemental Authority, Exh. 1, p. 5. Finally, it does not appear that the Ninth Circuit has determined that it in fact has jurisdiction to review the DEA interpretive rule under section 877.

hear constitutional and statutory challenges to INS procedures, the Court explained:

> [I]t is unlikely that a court of appeals would be in a position to provide meaningful review of the types of claims raised in this litigation. * * * Not only would a court of appeals * * * most likely not have an adequate record * * * but it also would lack the factfinding and record-developing capabilities of a federal district court. * * * [S]tatutes that provide for only a single level of judicial review in the court of appeals "are traditionally viewed as warranted only in circumstances where district court factfinding would unnecessarily duplicate an adequate administrate record—circumstances that are not present * * * where district court factfinding is essential given the inadequate administrative record."

McNary, 498 U.S. at 497, 111 S. Ct. 888 (citation omitted).

In summary, I conclude that this court has subject matter jurisdiction over plaintiff's and intervenors' broad statutory, procedural, and constitutional challenges to the Ashcroft directive. Because, however, in the inevitable appeal that will follow this decision the Ninth Circuit might decide otherwise, I hereby find that if there is a "want of jurisdiction" in this court, then in the interests of justice transfer to the Ninth Circuit Court of Appeals would be appropriate under 28 U.S.C. § 1631. *See Intern. Broth. of Teamsters v. Dept. of Transp.*, 932 F.2d 1292, 1298 (9th Cir. 1991) ("Jurisdictional substance, rather than procedural niceties or magic words, governs the propriety of transfers under section 1631").

II. *The Issue of Oregon's Standing*

Earlier in this case, defendants moved to dismiss the state of Oregon for lack of standing. The parties briefed the issue and I heard argument on it during the November 20, 2001, hearing. I then entered an order denying the motion "at this juncture."

Defendants have not again raised the issue of Oregon's standing and, despite an invitation to do so (TR at 23), failed to argue or even mention standing during the March 22, 2002, hearing. Although defendants' silence on this issue suggests that they now concede standing, to put this matter firmly to rest, I hereby find that the state of Oregon meets the statutory requirements for standing under the Declaratory Judgment Act, 28 U.S.C. § 2201, the Administrative Procedures Act, 5 U.S.C. § 702, as well as under any prudential principles that might apply. Oregon also meets the constitutional requirements for standing under Article III of the United States Constitution. Oregon has alleged and proved a sufficient injury to its sovereign and legitimate interest in the continued enforceability of its own statutes. See, *e.g.*, *Maine v. Taylor*, 477 U.S. 131, 137, 106 S. Ct. 2440, 91 L. Ed. 2d 110 (1986) ("a State clearly has a legitimate interest in the continued enforceability of its own statutes"); *Bowen v. Public Agencies Opposed to Social Sec.*, 477 U.S. 41, 50 n. 17, 106 S. Ct. 2390, 91 L. Ed. 2d 35 (1986) (state had "judicially cognizable interest in the preservation of its own sovereignty"); see also *State of Alaska v. U.S. Dept. of Transp.*, 868 F.2d 441, 443 n. 1 (D.C. Cir. 1989) ("Inasmuch as the States' sovereign interest in law enforce-

ment is sufficient to support standing, we need not delve into the issue of *parens patriae* standing").[13]

III. *Cross-Motions for Summary Judgment*

I now turn to the central substantive issue in this case, whether the Ashcroft directive, which declares that prescribing controlled substances to assist patient suicide is not a "legitimate medical purpose," is authorized under the CSA and its implementing regulations. Having carefully considered this matter, I conclude that nothing in the plain language of the CSA or its legislative history demonstrates Congress' intent to grant defendants the authority under the CSA to determine that prescribing controlled substances for purposes of physician-assisted suicide in compliance with Oregon law is not a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a).

I begin with the axiom that an administrative agency's power is limited to the authority delegated by Congress. *In re Altabon Foods, Inc.*, 998 F.2d 718, 719 (9th Cir. 1993), (*citing Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208, 109 S. Ct. 468, 102 L. Ed. 2d 493 (1988) ("agency's power to promulgate legislative regulations is limited to the authority delegated by Congress")). In defining the bounds of its regulatory authority, "'an agency may appropriately look to the

[13] As did the D.C. Circuit, I, too, decline to "delve into the issue of *parens patriae* standing." *State of Alaska v. U.S. Dept. of Transp.*, 868 F.2d 441, 443 n. 1 (D.C. Cir. 1989). I also note that defendants do not challenge the patient-intervenors' standing, and, recognizing that five of the initial nine patients in this case have died, have agreed to permit additional patients to join as plaintiff-intervenors to "keep the case alive" and get "this issue resolved." Transcript of Proceedings (March 22, 2002), pp. 90-91.

legislative history and underlying policies of its statutory grants of authority.'" *Altabon Foods*, 998 F.2d at 719 (quoting *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 132, 106 S. Ct. 455, 88 L. Ed. 2d 419 (1985)). This court's concomitant inquiry must "'focus on the language, structure, and legislative history of the CSA, with the primary goal of determin[ing] the intent of Congress.'" *Altabon Foods*, 998 F.2d at 719-20 (*quoting California v. Block*, 663 F.2d 855, 860 (9th Cir. 1981)).

1. *The Plain Language of the CSA Does Not Support the Ashcroft Directive.*

Defendants contend that the CSA authorizes the Ashcroft directive because provisions of the statute "plainly contemplate the existence of federal standards." Defendants' Memorandum, p. 20. According to defendants, certain provisions are "directly controlling here":

> that a "practitioner" must dispense controlled substances "in the course of professional practice" [§ 802(21)], that a controlled substance cannot be distributed "other than for a medical purpose" [§ 829(c)], and that a prescription "must be issued for a legitimate medical purpose" (21 C.F.R. § 1306.04) * * *.

Defendants' Memorandum, p. 20. Defendants also point to the rulemaking authority set forth in sections 821 and 871(b), the reference to "federal" control of drug trafficking in section 801(6), the reference to "this subchapter" in section 841(a), and the language that limits registered persons to dispensing controlled substances only "to the extent authorized by their registration and in conformity with the other provisions of this sub-

chapter." 21 U.S.C. § 822(b); *see* Defendants' Memorandum, pp. 20-21. Defendants find further significance in the CSA scheduling provisions, specifically sections 811(a)(1) (Attorney General may by rule assign controlled substances to schedules), and 812(b) (required findings for schedules I V include consideration of any "currently accepted medical use in treatment in the United States"). Defendants' Memorandum, p. 21.

Defendants urge the court to conclude that taken together, these gleaned bits and pieces of statutory language demonstrate Congress' intent that federal, rather than state, standards control the determination of what medical practices are authorized under the CSA with respect to controlled substances. In this regard, I agree with plaintiff that defendants' analysis, which focuses on "isolated words or sentences" to discern Congress' intent, is contrary to accepted principles of statutory construction. *U.S. Nat. Bank of Or. v. Independent Ins. Agents*, 508 U.S. 439, 455, 113 S. Ct. 2173, 124 L. Ed. 2d 402 (1993).

In *U.S. Nat. Bank*, the Supreme Court emphasized that it has "over and over * * * stressed that '[i]n expounding a statute, [the court] must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *Id.* at 455, 113 S. Ct. 2173 (*quoting United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122, 12 L. Ed. 1009 (1849) and noting that *Boisdore's* has been quoted in more than a dozen cases). Indeed, it is a "'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S. Ct. 1291, 146 L. Ed. 2d 121

(2000); *see also Lexecon Inc. v. Milberg Weiss Bershad Hynes*, 523 U.S. 26, 36, 118 S. Ct. 956, 140 L. Ed. 2d 62 (1998) (central tenet of interpretation is that statute is to be considered in all its parts when construing any one of them).

Thus,

> [a] court must * * * interpret the statute "as a symmetrical and coherent scheme," * * * and "fit, if possible, all parts into an harmonious whole" * * *. In addition, [a court] must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such * * * political magnitude to an administrative agency.

FDA v. Brown & Williamson, 529 U.S. at 133, 120 S. Ct. 1291 (citations omitted).

It is undisputed that under the CSA, the Attorney General and the DEA have broad authority to regulate controlled substances. No provision of the CSA, however, alone (as defendants urge) or viewed as a "symmetrical and coherent scheme" demonstrates or even suggests that Congress intended to delegate to the Attorney General or the DEA the authority to decide, as a matter of national policy, a question of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice.

Nor, as defendants propose, did the 1984 amendments to the CSA delegate such authority. As amended, section 823(f) permits the Attorney General to deny an application for registration as "inconsistent with the public interest" after consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) such other conduct which may threaten the public health and safety.

The revocation section, § 824(a)(4), as amended, includes as a ground for revocation or suspension "such acts as would render his registration under section 823 * * * inconsistent with the public interest as determined under such section." Defendants read these amendments, together with 21 C.F.R. § 1306.04, as supplying evidence that Congress intended to expand the Attorney General's and the DEA's authority to include the power to define the parameters of legitimate medical practices. I do not, however, read the CSA or the 1984 amendments as containing—either explicitly or implicitly—such a remarkable grant of power.

2. *The Legislative History of the CSA Does Not Support the Ashcroft Directive.*

As observed by Professor William Funk of the Lewis and Clark Law School in his review of Justice Scalia's essay[14] on legislative interpretation:

> The legitimacy of legislative history as a means of interpreting statutes, at least when they are unclear, is, rightly or wrongly, well established. Other than Justice Thomas, no Justice seems interested in adopting Justice Scalia's rejection of legislative history or his rejection of the notion of legislative intent.

William Funk, *Review Essay Faith in Texts—Justice Scalia's Interpretation of Statutes and the Constitution: Apostasy for the Rest of Us?* 49 Admin. L. Rev. 825 (1997). Both sides in this controversy resort to certain congressional comments and reports to buttress their views of what Congress intended in enacting and amending the CSA. Nothing in the legislative history suggests, however, that anyone in Congress intended the CSA to restrict or proscribe prescriptions for controlled substances that might be used legitimately under state law to assist suicide or hasten death. To the contrary, the legislative history of both the 1970 enactment and the 1984 amendments overwhelming support a conclusion that Congress' intent was to address problems of drug abuse, drug trafficking, and diversion of drugs from legitimate channels to illegiti-

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[14] A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW. An Essay by Antonin Scalia with Commentary by Amy Gutmann, editor, Gordon S. Wood, Laurence H. Tribe, Mary Ann Glendon, and Ronald Dworkin. Princeton: Princeton University Press, 1997.

mate channels. *See United States v. Moore*, 423 U.S. 122, 134-35, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) ("Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant").

The best defendants can produce in the way of supportive legislative history is a vague comment by one congressman, Representative Gillman, to the effect that by amending the CSA, Congress wanted to "make it easier" for the DEA to suspend or revoke the authority of physicians who write or dispense prescriptions in a way that is threatening to public health or safety, and an equally curious reference from the House Committee report, which states:

> Although the Committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutors of what constitutes appropriate methods of professional practice.

Defendants' Memorandum, pp. 16-17.

What does this add to the issue at hand? I have already explained that the core objective of the CSA was to permit federal prosecution of drug dealers, drug abusers, and "practitioners" who engage in the illegal diversion and distribution of drugs. Defendants cannot seriously conclude from the above-quoted language that Congress delegated to federal prosecutors the authority to define what constitutes legitimate *medical* practices.[15] To state the proposition is to refute it. Federal prosecutors have never possessed such powers, and the vagueness of the reference would render any alleged violation based on a prosecutor's subjective views about medical practice patently unenforceable.

Having served in the state legislature, I do not give much credence to floor speeches or even committee reports as representing the intent of a legislative body. As many have observed in watching Congress at work, members of Congress often speak about legislative intent to an empty room, or place material prepared by staff, lobbyists and the like into the congressional record. To construe this as revealing legislative intent defies reality and more often than not ignores the plain meaning of the statute in favor of the subjective beliefs of individual members of Congress, an extremely unreliable approach to statutory interpretation.[16] As Justice Scalia observed in his essay[17] and in his concurring opinion in *Conroy v. Aniskoff*, 507 U.S. 511, 519, 113 S. Ct. 1562, 123 L. Ed. 2d 229 (1993):

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[15] The case law defendants cite belies this conclusion. As discussed in the next portion of this decision, even in cases where a doctor or pharmacist is a "drug pusher" or blatantly operates a "pill mill," the issue of whether the conduct is outside the normal course of professional or medical practice is entrusted to a jury, to decide the issue as mixed subjective-objective question of fact under instructions based on community standards, not on some national standard adopted as a federal regulation.

[16] In contrast, carefully prepared advisory committee notes, when officially adopted by a legislative body, can be exceedingly helpful in interpreting statutes and rules. *E.g.*, Federal Rules of Civil Procedure; Federal Rules of Evidence.

[17] *See* footnote 14, *supra*.

> Judge Harold Leventhal used to describe the use of legislative history as the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends.

Here, neither side has presented any convincing relevant comment from friend or foe to reliably demonstrate that Congress ever considered assisted suicide in enacting or amending the CSA. Moreover, no legislative history supports defendants' theory that Congress intended the 1984 amendments to "alter[ ] the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste Agency v. Army Corps of Engineers*, 531 U.S. 159, 173, 121 S. Ct. 675, 148 L. Ed. 2d 576 (2001) (citation omitted). Thus, I need not determine the merit or lack of merit of the legislative history, simply because there is none on point.

3. *The Case Law Does Not Support the Ashcroft Directive.*

The cases defendants cite as "equally clear that federal law determines what medical practices are authorized by the CSA,"[18] *United States v. Moore*, *supra*, *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975), *United States v. Hayes*, 794 F.2d 1348 (9th Cir. 1986), *United States v. Boettjer*, 569 F.2d 1078 (9th Cir. 1978), and *U.S. v. Leal*, 75 F.3d 219 (6th Cir. 1996), do not advance their position. All involved criminal proceedings against DEA registered physicians or pharmacists whose activities fell far outside any definition of the usual or accepted course of professional medical practice. In none of the cases was a doctor or

[18] Defendants' Memorandum, p. 21.

pharmacist prosecuted and convicted under the CSA for legal medical actions taken in compliance with state law, which is precisely what the Ashcroft directive would permit if allowed to stand.

In *Moore*, for example, the defendant doctor "acted as a large-scale 'pusher' not as a physician," and admitted that he did not observe generally accepted medical practices. 423 U.S. at 126, 143. In *Rosenberg*, the evidence established that "[w]hen a doctor acts as Dr. Rosenberg did in this case, he can appropriately be called a trafficker in drugs." 515 F.2d at 196. The *Rosenberg* court was careful to note, however, that the phrase "in the course of professional medical practice" as used in the CSA "clearly means that a doctor is not exempt from the statute when he takes actions *that he does not in good faith believe are for legitimate medical purposes*," plainly a subjective standard. 515 F.2d at 197 (emphasis added).[19]

In both *Hayes* and *Boettjer*, the quoted language on which defendants rely for a "federal" standard of medicine actually was part of the trial courts' jury instructions. *Hayes*, 794 F.2d at 1351; *Boettjer*, 569 F.2d at

[19] Defendants' reliance on *Rosenberg* for the proposition that federal law determines what medical practices are authorized by the CSA is misleading. In the portion of the opinion that defendants quote, the Ninth Circuit's comments were directed to the doctor's constitutional argument that whether he was acting in the course of his professional practice must be determined by the state court, because " 'direct control of medical practice in the states is beyond the power of the federal government.' " *Rosenberg*, 515 F.2d at 198 (citation omitted). The Ninth Circuit did not hold that the CSA authorizes direct agency determination of what constitutes the ordinary course of professional practice, instead, the court held only that the CSA is constitutional under the Tenth Amendment.

1081. Nothing in either opinion suggests that the Ninth Circuit approved or adopted a federal test for "legitimate medical purpose" or "usual course." The last case defendants cite, *United States v. Leal*, concerned a "pill mill" operated by a physician and a pharmacy. The *Leal* court rejected defendant pharmacist's argument that he was entitled to a jury instruction concerning his duties as a pharmacist under state law, because as a DEA registrant, the CSA imposed a "federal duty on *Leal* to be vigilant in filling prescriptions, so as to avoid filling those that were issued for a non-medical purpose. Whether state law imposes an equivalent civil or criminal duty is irrelevant." *Leal*, 75 F.3d at 227. The *Leal* court did not, as defendants would like this court to infer, hold that the federal law gives content to what is or is not a "medical purpose."[20]

IV. *Summary*

The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. State statutes, state medical boards, and state regulations control the practice of medicine. The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board. To allow an attorney general—an appointed executive whose tenure depends entirely on whatever administration occupies the White House—to determine the legitimacy of a particular medical practice

[20] I note that defendants seem to have abandoned the notion, espoused in the Ashcroft directive, that the Supreme Court's decision in *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001), is somehow controlling on the issues presented here.

without a specific congressional grant of such authority would be unprecedented and extraordinary. As stated, the practice of medicine is based on state standards, recognizing, of course, national enactments that, within constitutional limits, specifically and clearly define what is lawful and what is not.[21] Without doubt there is tremendous disagreement among highly respected medical practitioners as to whether assisted suicide or hastened death is a legitimate medical practice, but opponents have been heard and, absent a specific prohibitive federal statute, the Oregon voters have made the legal, albeit controversial, decision that such a practice is legitimate in this sovereign state.

The Ashcroft directive attempts to define the term "legitimate medical purpose" to exclude use of controlled substances for otherwise legal physician-assisted suicide where Congress failed to do so despite multiple opportunities. Obviously, Congress knows how to do so, as manifested in its abandoned attempts to restrict assisted suicide nationwide. Because former Attorney General Reno concluded that the CSA has no application to the Oregon Act, Representative Hyde introduced two bills in the House of Representatives to specifically address the Oregon Act. The first bill, the Lethal Drug Use Prevention Act of 1998, would have amended the CSA to directly authorize the suspension or revocation of a practitioner's DEA registration if the

[21] For example, in section 4 of Title I of the 1970 CSA, 42 U.S.C. § 257a, Congress expressly required the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction. . . ." *United States v. Moore*, 423 U.S. 122, 144, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975).

registrant intentionally dispensed or distributed a controlled substance for the purpose of assisting the suicide or euthanasia of another individual. The second bill, the Pain Relief Promotion Act, attempted to clarify the CSA to provide that the alleviation of pain is a legitimate medical purpose, but that the CSA did not permit the use of controlled substances to cause death or assist in a suicide. While the second bill passed the House, neither bill passed the Senate, and neither was signed into law.

Even though both acts failed in Congress, certain congressional leaders made a good faith effort to get through the administrative door that which they could not get through the congressional door, seeking refuge with the newly-appointed Attorney General whose ideology matched their views, and this is precisely what occurred. The Executive Branch immediately began its efforts to re-write the law to achieve its goal of abolishing assisted suicide anywhere. Although congressional action attempting to control matters traditionally left to the state may raise constitutional issues for any future legislation in this field, suffice it to say that at this juncture, neither the U.S. Constitution nor the Bill of Rights speaks to assisted suicide, neither providing for it as a personal right nor prohibiting it.

I again emphasize that I resolve this case as a matter of statutory interpretation, and my interpretation of the statutory text and meaning is that the CSA does not prohibit practitioners from prescribing and dispensing controlled substances in compliance with a carefully-worded state legislative act. Thus, the Ashcroft directive is not entitled to deference under any

standard[22] and is invalid. I also emphasize that my task is not to criticize those who oppose the concept of assisted suicide for any reason. Many of our citizens, including the highest respected leaders of this country, oppose assisted suicide. But the fact that opposition to assisted suicide may be fully justified, morally, ethically, religiously or otherwise, does not permit a federal statute to be manipulated from its true meaning to satisfy even a worthy goal. As the Supreme Court has warned, courts should be "out of the business of reviewing the wisdom of statutes," *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15, 96 S. Ct. 2882, 49 L. Ed. 2d 752 (1976), a proposition not to be taken "cum grano salis" (with a grain of salt). *Barrick Gold Exploration, Inc. v. Hudson*, 47 F.3d 832, 836 (6th Cir. 1995) (commenting on Easterbrook, *The Constitution of Business*, 11 Geo. Mason U.L. Rev. 53 (1988)).

CONCLUSION

For the reasons stated, plaintiff's motion for summary judgment (# 111) and intervenors' motions for summary judgment or partial summary judgment (## 85, 101) are granted in part and moot in part; patients-intervenors' motion for class certification (# 41) is denied; and defendants' motion to dismiss and alternative motion for summary judgment (# 133) is denied. The Permanent Injunction entered concurrently with this Opinion and Order shall be effective immediately upon filing. Any other pending motions are denied as moot.

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[22] *See* Oregon's Memorandum in Support, pp. 16-18, for a discussion of the various levels of deference, none of which governs here.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 02-35587

STATE OF OREGON, PLAINTIFF-APPELLEE

v.

JOHN ASHCROFT, ATTORNEY GENERAL, IN HIS OFFICIAL CAPACITY AS UNITED STATES ATTORNEY GENERAL, ET AL., DEFENDANTS-APPELLANTS

v.

PETER A. RASMUSSEN, ET AL.,
PLAINTIFF-INTERVENORS-APPELLEES

[Filed August 11, 2004]

ORDER

Before: Lay* , Wallace, and Tallman, Circuit Judges.

Judges Lay and Tallman have voted to deny the petition for panel rehearing; Judge Tallman has voted to deny the petition for rehearing en banc and Judge Lay so recommends. Judge Wallace has voted to grant the petition for panel rehearing and the petition for rehearing en banc.

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* Honorable Donald P. Lay, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for panel rehearing and the petition for rehearing en banc are denied.

APPENDIX D

RULES and REGULATIONS

DEPARTMENT OF JUSTICE

Office of the Attorney General

21 CFR Part 1306

[AG Order No. 2534-2001]

Dispensing of Controlled Substances To Assist Suicide

Friday, November 9, 2001

AGENCY: Department of Justice.

ACTION: Interpretive rule.

SUMMARY: For the reasons provided in the memorandum set forth below, the Attorney General has determined that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 CFR 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act. Such conduct by a physician registered to dispense controlled substances may "render his registration . . . inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). The Attorney General's conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless

of the condition of the person whose suicide is assisted. The Attorney General recognizes, however, that pain management is a legitimate medical purpose justifying a physician's dispensing of controlled substances. Finally, the Attorney General's determination makes no change in the current standards and practices of the DEA in any State other than Oregon.

EFFECTIVE DATE: November 9, 2001.

FOR FURTHER INFORMATION CONTACT: Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, telephone 202-307-7297.

SUPPLEMENTARY INFORMATION: The text of the Attorney General's memorandum follows:

Memorandum for Asa Hutchinson,
Administrator, The Drug Enforcement Administration

From: John Ashcroft, Attorney General

Subject: *Dispensing of Controlled Substances to Assist Suicide*

As you are aware, the Supreme Court reaffirmed last term that the application of federal law regulating controlled substances is uniform throughout the United States and may not be nullified by the legislative decisions of individual States. See *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001). In light of this decision, questions have been raised about the validity of an Attorney General letter dated June 5, 1998, which overruled an earlier Drug Enforcement Administration (DEA) determination that narcotics and other dangerous drugs controlled by federal law may not be dispensed consistently with the Con-

trolled Substances Act, 21 U.S.C. 801-971 (1994 & Supp. II 1996) (CSA), to assist suicide in the United States. Upon review of the *Oakland Cannabis* decision and other relevant authorities, I have concluded that the DEA's original reading of the CSA—that controlled substances may not be dispensed to assist suicide—was correct. I therefore advise you that the original DEA determination is reinstated and should be implemented as set forth in greater detail below.

The attached Office of Legal Counsel opinion, entitled "*Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under The Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act*" (June 27, 2001) ("OLC Opinion") (attached) sets forth the legal basis for my decision.

1. *Determination on Use of Federally Controlled Substances to Assist Suicide.* For the reasons set forth in the OLC Opinion, I hereby determine that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 CFR § 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA. Such conduct by a physician registered to dispense controlled substances may "render his registration * * * inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). This conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted.

I hereby direct the DEA, effective upon publication of this memorandum in the **Federal Register**, to enforce and apply this determination, notwithstanding anything

to the contrary in the June 5, 1998, Attorney General's letter.

2. *Use of Controlled Substances to Manage Pain Promoted.* Pain management, rather than assisted suicide, has long been recognized as a legitimate medical purpose justifying physicians' dispensing of controlled substances. There are important medical, ethical, and legal distinctions between intentionally causing a patient's death and providing sufficient dosages of pain medication necessary to eliminate or alleviate pain.

3. *No Change in Current DEA Policies and Enforcement Practices Outside Oregon.* The reinstated determination makes no change in the current standards and practices of the DEA in any State other than Oregon. Former Attorney General Janet Reno's June 5, 1998, letter relating to this matter emphasized that action to revoke the DEA registration of a physician who uses federally controlled substances to assist a suicide "may well be warranted * * * where a physician assists in a suicide in a state that has not authorized the practice under any conditions." The reinstated determination does not portend any increase in investigative activity or other change from the manner in which the DEA presently enforces this policy outside of Oregon.

4. *Enforcement in Oregon.* Under 3 Oregon Revised Statutes (O.R.S.) § 127.855 (1999), an attending physician who writes a prescription for medication to end the life of a qualified patient must document the medication prescribed. Under 3 O.R.S. § 127.865(1)(b) (1999), the State of Oregon's Health Division must require any health care provider upon dispensing medication pursuant to the Death with Dignity Act to file a copy of the

dispensing record with the Division. Those records should contain the information necessary to determine whether those holding DEA registrations who assist suicides in accordance with Oregon law are prescribing federally controlled substances for that purpose in violation of the CSA as construed by this Memorandum and the attached OLC Opinion.

The Department has the authority to take appropriate measures to obtain copies of any such reports or records sent to the Oregon State Registrar. See 21 U.S.C. 876. When inspection of these documents discloses prohibited prescription of controlled substances to assist suicide following the effective date of this memorandum, then appropriate administrative action may be taken in accordance with 21 CFR §§ 1316.41 to 1316.68 (2001).

Thus, it should be possible to identify the cases in which federally controlled substances are used to assist suicide in Oregon in compliance with Oregon law by obtaining reports from the Oregon State Registrar without having to review patient medical records or otherwise investigate doctors. Accordingly, implementation of this directive in Oregon should not change the DEA's current practices with regard to enforcing the CSA so as materially to increase monitoring or investigation of physicians or other health care providers or to increase review of physicians' prescribing patterns of controlled substances used for pain relief.

5. *Distribution.* Please ensure that this Memorandum and the OLC opinion on which it is based are promptly distributed to appropriate DEA personnel, especially those with authority over the enforcement of the CSA in Oregon.

Attachment

Note: The attachment containing the Office of Legal Counsel opinion dated June 27, 2001, does not appear in the **Federal Register**. It is available from the Drug Enforcement Administration at the address listed in **FOR FURTHER INFORMATION CONTACT.**

Dated: November 6, 2001.

John Ashcroft,
Attorney General.

APPENDIX E

SEAL

U.S. Department of Justice
Office of Legal Counsel

Office of the Deputy Assistant Attorney General *Washington, D.C. 20530*

June 27, 2001

MEMORANDUM FOR THE ATTORNEY GENERAL

FROM: Sheldon Bradshaw
Deputy Assistant Attorney General

Robert J. Delahunty
Special Counsel

RE: *Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under The Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act*

You have asked for our opinion whether a physician who assists in a patient's suicide by prescribing a controlled substance has a "legitimate medical purpose" within the meaning of a regulation of the Drug Enforcement Administration (DEA), 21 C.F.R. § 1306.04(a) (2000),[1] if the physician is immune from liability under a

[1] The DEA regulation was promulgated pursuant to a delegation of the Attorney General's broad authorities under the Controlled Substances Act, 21 U.S.C. §§ 801-971 (1994 & Supp. II 1996) (the CSA or Act), to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions," 21 U.S.C. § 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this [title]." *Id.*, § 871(b). *See also id.*, § 871(a) (authority of Attorney General to delegate CSA functions); 28 C.F.R. § 0.100 (2000) (delegation to DEA); *Touby v. United States*, 500 U.S. 160, 169 (1991) (upholding Attorney General's authority to delegate CSA function to DEA).

state law such as the Oregon "Death with Dignity Act" for assisting in a suicide in such a manner.[2] In our view, assisting in suicide, even in a manner permitted by state law, is not a "legitimate medical purpose" under the DEA regulation, and accordingly dispensing controlled substances for this purpose violates the Controlled Substances Act, which the DEA regulation implements.

Background

The Oregon "Death with Dignity Act," which legalized physician-assisted suicide under certain circumstances, was originally approved by Oregon voters on November 8, 1994, and went into effect on October 27, 1997.[3] Prior to the effective date of the Oregon law, Representative Henry J. Hyde, Chairman of the House Judiciary Committee, and Senator Orrin G. Hatch,

[2] The "Death with Dignity Act" is codified at 3 Oregon Revised Statutes (O.R.S.) §§ 127.800-127.995 (1999).

[3] On the circumstances surrounding the adoption of the Oregon "Death with Dignity Act" and a description of its provisions, *see generally* Mark C. Siegel, *Lethal Pity: The Oregon Death With Dignity Act, Its Implications for the Disabled, and the Struggle for Equality in an Able-Bodied World*, 16 Law & Ineq. 259, 270-76 (1998).

Chairman of the Senate Judiciary Committee, wrote to the Administrator of the DEA, Thomas A. Constantine, requesting a determination whether the CSA prohibits the use of controlled substances for the purpose of assisting in a suicide.[4]

Administrator Constantine replied on November 5, 1997, concluding "that delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose'" and thus would violate the CSA.[5]

Within a month, the Oregon Deputy Attorney General, David Schuman, wrote to the United States Department of Justice on December 3, 1997, arguing that "the CSA is addressed to the problems of the abuse and trafficking of controlled substances. In enacting and later amending the CSA, Congress had no intention of regulating medical practices that are legal under state law and that have no relation to drug abuse

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[4] Letter for The Honorable Thomas A. Constantine, Administrator of the Drug Enforcement Administration, from Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives, and Chairman Orrin G. Hatch, Committee on the Judiciary, U.S. Senate, July 29, 1997 ("In our view, assisting in a suicide by prescribing or filling a prescription for a controlled substance cannot be a 'legitimate medical purpose' under DEA regulations, especially when the practice is not reasonable and necessary to the diagnosis and treatment of disease and injury, legitimate health care, or compatible with the physician's role as healer.") (Hyde Letter).

[5] Letter for Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives, from The Honorable Thomas A. Constantine, Administrator of the Drug Enforcement Administration of the United States, Nov. 5, 1997, at 1-2 (Constantine Letter).

or trafficking."[6] Deputy Attorney General Schuman concluded that the DEA had no authority to regulate medical practices authorized by state law and unrelated to drug abuse or trafficking.

On June 5, 1998, Attorney General Janet Reno reversed the interpretation of DEA Administrator Constantine, concluding that "the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Specifically, Attorney General Reno stated: "There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice."[7]

I. *Physicians Are Regulated Under the Controlled Substances Act*

The basic domestic drug trafficking provision of the CSA, 21 U.S.C. § 841, governs physicians' prescriptions of controlled substances. Section 841(a)(1) makes it unlawful for "any person knowingly or intentionally . . . to . . . dispense, a controlled substance." The term

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[6] Letter for Mr. Jonathan Schwartz, [Principal Associate Deputy] Attorney General, U.S. Department of Justice, Office of the [Deputy] Attorney General, from Mr. David Schuman, Oregon Deputy Attorney General, Dec. 3, 1997, at 7 (Oregon Deputy Attorney General Letter).

[7] Letter for The Honorable Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives, from The Honorable Janet Reno, Attorney General of the United States, June 5, 1998, at 1 ("Adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the [CSA]") (1998 Letter).

"dispense" is defined to "mean[] to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner . . . ." 21 U.S.C. § 802(10). A "practitioner" includes a "physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . a controlled substance in the course of professional practice." *Id.*, § 804(21).

Although section 841(a)(1) generally prohibits the dispensing of controlled substances, the statute does permit such action if "authorized by this subchapter." 21 U.S.C. § 841(a). One such form of authorization is found in the CSA's provisions dealing with physician "registration." *See id.*, § 822(b) ("Persons registered by the Attorney General . . . to . . . dispense controlled substances . . . are authorized to . . . dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter."). Physicians may apply to the DEA (which acts here as the Attorney General's delegate) for registration permitting them to prescribe and administer controlled substances. Section 823(b) provides that the DEA shall register qualified applicants unless it "determines that . . . such registration is inconsistent with the public interest." This determination is to be based on any of five factors identified in the statute, including "such other factors as may be relevant to and consistent with the public health and safety." *Id.*, § 823(b)(5).

"[T]he scheme of the [CSA], viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.' . . . Implicit in the registration of a physician is the understanding that

he is authorized only to act 'as a physician.' . . . [R]egistration is limited to the dispensing and use of drugs 'in the course of professional practice or research.' Other provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits." *United States v. Moore*, 423 U.S. 122, 140-42 (1975). Although section 841(a) does not, in terms, state that a physician is authorized to dispense controlled substances only for a legitimate medical purpose, that limitation appears to be implicit in the statute, *see Moore*, 423 U.S. at 137, n.13, and has been made explicit by DEA regulation.[8] The relevant regulation reads:

> A prescription issued for a controlled substance to be effective must be issued *for a legitimate medical purpose* by an individual practitioner acting in the usual course of his professional practice. . . . An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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[8] The courts have found no distinction between the statutory phrase "in the course of professional practice" and the regulatory phrase, "legitimate medical purpose." *See United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975), *cert. denied*, 423 U.S. 1031 (1975); *cf. United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978), *cert. denied*, 439 U.S. 1048 (1978); *United States v. Plesons*, 560 F.2d 890, 897, n.6 (8th Cir. 1977), *cert. denied*, 434 U.S. 966 (1977).

21 C.F.R. § 1306.04(a) (emphasis added).

Where a physician dispenses controlled substances without a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a), the physician violates several provisions of the CSA, including §§ 829 and 841(a)(1). If such dispensing without a legitimate medical purpose is proven in a criminal case, the physician may be subject to criminal penalties under 21 U.S.C. §§ 841(a)(1) (felony) and 842(a)(1) (misdemeanor). *See Moore* (holding that registered physician can be prosecuted and convicted under § 841(a)(1) for dispensing controlled substances outside the usual course of professional practice). Even without a criminal prosecution or conviction, the DEA may initiate administrative proceedings to suspend or revoke the registration of a physician based on evidence that the physician dispensed controlled substances without a legitimate medical purpose under 21 C.F.R. § 1306.04(a). In an administrative proceeding, the Government must prove, by a preponderance of the evidence, that the physician dispensed in violation of § 1306.04(a), and that, as a result, the physician's continued registration would be inconsistent with the public interest. *See* 21 U.S.C. § 824(a)(4) (applying public interest standard of § 823(f) to administrative proceedings for suspension or revocation of registration granted under § 823); *see generally Robert G. Hallermeier, M.D., Continuation of Registration with Restrictions*, 62 Fed. Reg. 26,818 (1997) (administrative proceeding in which DEA sought revocation of physician's federal registration).[9] Nothing in the language of the

[9] We note that practitioners have lost or been denied Federal registrations necessary to prescribe controlled substances because they have prescribed controlled substances used in suicides and other lethal overdoses. *See, e.g., Hugh I. Schade, M.D., Denial of*

CSA or of the relevant DEA regulations requires that the physician be shown to have violated state law in order to be subject to criminal sanctions under §§ 829 or 841(a), or to suspension or revocation of federal registration under § 824(a)(4). Indeed, of the five separate grounds listed in § 824(a)(4) for adverse administration action, only two directly concern state law sanctions.[10] Further, as we shall discuss in detail below, *see infra* at 17-19, Congress added the "public interest" standard in § 824(a)(4) in order to permit the Attorney General to take adverse administrative action against a registrant in cases in which the registrant's wrongful conduct might not have been sanctioned or sanctionable under state law.

II. *Dispensing Controlled Substances to Assist in Suicide Does Not Serve a "Legitimate Medical Purpose"*

We understand that physician-assisted suicide typically involves the use of a lethal dose of a combination

Application, 60 Fed. Reg. 56,354 (1995); *José R. Castro, M.D., Denial of Application*, 62 Fed. Reg. 16,189 (1997); *Samuel Fertig, M.D., Denial of Application*, 49 Fed. Reg. 6,577 (1984); *Murray J. Walker, M.D., Revocation of Registration*, 55 Fed. Reg. 5,306 (1990); *see also Townwood Pharmacy, Revocation of Registration*, 63 Fed. Reg. 8,477 (1998).

[10] Section 824(a)(2) authorizes the Attorney General to suspend or revoke a registration upon a finding that the registrant "has been convicted of a felony under . . . any . . . law . . . of any State, relating to any . . . controlled substance," while section 824(a)(3) authorizes such action if the registrant "has had his State license or registration suspended, revoked, or denied . . . and is no longer authorized by State law to engage in . . . dispensing . . . controlled substances . . . or has had the suspension, revocation, or denial of his registration recommended by competent State authority."

of drugs, including controlled substances. First, the patient is sedated using either a barbiturate (*e.g.*, sodium pentothal), or an opiate (*e.g.*, morphine). Then, one or more drugs are used to paralyze the muscles and/or to stop the heart. The sedatives involved in these procedures are controlled substances under the CSA. Most lawfully available opiates and barbiturates are in Schedule II of the CSA, the most strictly regulated category of substances available for non-research purposes. *See* 21 C.F.R. § 1308.12(b), (c), (e) (2000).

In our opinion, assisting in suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. § 1306.04(a) that would justify a physician's dispensing controlled substances. That interpretation, which the DEA itself originally adopted before being overruled by Attorney General Reno, is the best reading of the regulatory language: it is firmly supported by the case law, by the traditional and current policies and practices of the Federal government and of the overwhelming majority of the States, and by the dominant views of the American medical and nursing professions.

A. *Case Law*

The case law demonstrates that the CSA forbids dispensing controlled substances except in the course of accepted medical practice, and that physician-assisted suicide is outside the boundaries of such practice.

In *Moore*, the Supreme Court in effect approved a jury instruction under which a physician would be held criminally liable for dispensing controlled substances in violation of 21 U.S.C. § 841(a) unless the physician was acting "in the usual course of professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States."

Moore, 423 U.S. at 139. The lower courts have followed *Moore* in requiring that a physician's actions conform to standards "generally recognized and accepted" throughout the nation. For example, in *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986), the court stated that:

> To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area. As the Supreme Court noted in *Moore*, "Congress intended the CSA to strengthen rather than weaken the prior drug laws."

As the courts have found, physician-assisted suicide has never been, and is not now, a generally recognized and accepted medical practice in the United States. On the contrary, the American legal system and the American medical profession alike have consistently condemned the practice in the past and continue to do so.

In *Washington v. Glucksberg*, 521 U.S. 702 (1997), the Supreme Court upheld a state prohibition against causing or aiding a suicide against a challenge that, as applied to physicians assisting terminally ill, mentally competent patients, the prohibition offended the requirements of substantive due process. *See id.* at 709, n.6 (describing holding). The Court began its analysis by examining "our Nation's history, legal traditions, and practices," *id.* at 710. The Court found that "[i]n almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide. The States' assisted-suicide bans are not innovations. Rather, they

are longstanding expressions of the States' commitment to the protection and preservation of all human life" (footnote omitted). *Id.*[11] After tracing "the Anglo-American common law tradition" that "for over 700 years" "has punished or otherwise disapproved of both suicide and assisted suicide," *id.* at 711, the Court referred to the Oregon "Death With Dignity Act," which legalized physician-assisted suicide for competent, terminally ill adults. The Court's discussion made plain that the Oregon statute represented an exceptional case, contrary both to longstanding historical practices and to contemporary trends in the law:

> Since the Oregon vote, many proposals to legalize assisted-suicide laws have been and continue to be introduced in the States' legislatures, but none has been enacted. And just last year [*i.e.*, 1996], Iowa and Rhode Island joined the overwhelming majority of States explicitly prohibiting assisted suicide. . . . Also, on April 30, 1997, President Clinton signed the Federal Assisted Suicide Funding Restriction Act of 1997, which prohibits the use of federal funds in support of physician-assisted suicide.

Id. at 717-18 (citations and footnotes omitted). Further, the Court discussed the "serious, thoughtful examinations of physician-assisted suicide and other similar issues" now going on in the States. *Id.* at 719. It referred in particular to the work of New York State's

[11] *Accord Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 280 (1990) ("As a general matter, the States—indeed, all civilized nations—demonstrate their commitment to life by treating homicide as a serious crime. Moreover, the majority of States in this country have laws imposing criminal penalties on one who assists another to commit suicide.").

Task Force on Life and the Law, a commission composed of doctors, ethicists, lawyers, religious leaders and interested laymen charged with recommending public policy on issues raised by medical advances. The Court noted that after studying physician-assisted suicide, the Task Force had unanimously concluded that "[l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable. . . . [T]he potential dangers of this dramatic change in public policy would outweigh any benefit that might be achieved." *Id.* (internal quotation marks and citation omitted; ellipses in original).

Summarizing its review of the American legal tradition's view of assisted suicide, the Court said:

> Attitudes toward suicide itself have changed since Bracton, but our laws have consistently condemned, and continue to prohibit, assisting suicide. Despite changes in medical technology and notwithstanding an increased emphasis on the importance of end-of-life decisionmaking, we have not retreated from this prohibition.

Id.

B. *State and Federal Policy*

As detailed in *Washington v. Glucksberg*, state law and policy, with the sole exception of Oregon's, emphatically oppose assisted suicide. Assisted suicide has long been prohibited at common law, *see Glucksberg*, 521 U.S. at 711,[12] and at least forty States and terri-

[12] *See generally* Thomas J. Marzen, Mary K. O'Dowd, Daniel Crone & Thomas J. Balch, *Suicide: A Constitutional Right?*, 24 Duq. L. Rev. 1, 71-75 (1985).

tories have laws explicitly prohibiting the practice.[13] "In the two hundred and five years of our [national] existence no constitutional right to aid in killing oneself has ever been asserted and upheld by a court of final jurisdiction." *Compassion in Dying v. Washington*, 49 F.3d 586, 591 (9th Cir. 1995) (Noonan, J.), *rehearing en banc granted*, 62 F.3d 299 (9th Cir. 1995); *vacated*, 79 F.3d 790 (9th Cir. 1996) (en banc) (Reinhardt, J.) (State could not constitutionally prohibit physician-assisted suicide in cases of terminally ill competent adults), *rev'd sub nom. Washington v. Glucksberg*, 521 U.S. 702 (1997). The only state supreme court to decide the matter has rejected recognition of an enforceable right to assisted suicide under that State's constitution. *Krischer v. McIver*, 697 So. 2d 97 (Fla. 1997).

State statutes banning assisted suicide trace back a century or more in many cases. They have not been kept on the books through oversight or neglect:

> Many jurisdictions have expressly reconsidered these laws in recent years and reaffirmed them. In 1980, the American Law Institute conducted a thorough review of state laws on assist[ed] suicide in the United States and acknowledged the continuing widespread support for criminalization. Accordingly, it endorsed two criminal provisions of its own. In the 1990s, both New York and Michigan convened blue-ribbon commissions to consider the possibility of legalizing assisted suicide and euthanasia. The New York commission issued a thoughtful and detailed report unanimously recommending

[13] *See* Christine Neylon O'Brien & Gerald A. Madek, *Physician-Assisted Suicide: New Protocol for a Rightful Death*, 77 Neb. L. Rev. 229, 275, n.314 (1998).

> the retention of existing laws against assisting suicide and euthanasia. The Michigan panel divided on the issue, but the state legislature subsequently chose to enact a statute strengthening its existing common law ban against assisted suicide. . . . Meanwhile, repeated efforts to legalize the practice —in state legislatures and by popular referenda —have met with near-total failure.

Neil M. Gorsuch, *The Right to Assisted Suicide and Euthanasia*, 23 Harv. J. L. & Pub. Pol'y 599, 639-41 (2000) (footnotes omitted).

Federal policy fully accords with the views that prevail in every State except Oregon. As noted in *Glucksberg*, the Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, 111 Stat. 23, was signed into law on April 30, 1997. The Act was approved in the House of Representatives by a 398-to-16 vote and in the Senate by a 99-0 vote. The Act bans Federal funding of assisted suicide, euthanasia, or mercy killing through Medicaid, Medicare, military and Federal employee health plans, the veterans health care system, or other Federally funded programs. In the "Findings" preceding the Act's substantive restrictions, Congress stated that "[a]ssisted suicide, euthanasia, and mercy killing have been criminal offenses throughout the United States and, under current law, it would be unlawful to provide services in support of such illegal activities." *Id.* at § 2(a)(2). Then, after taking note that the Oregon "Death With Dignity Act" might soon become operative, *see id.* at § 2(a)(3), Congress determined that it would "not provid[e] Federal financial assistance in support of assisted suicide, euthanasia, and mercy killing and intends that Federal funds not be used to promote such activities." *Id.* at § 2(a)(4). In

general, Congress stated that its purpose was "to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual." *Id.* at § 2(b).

Even before the enactment of the Assisted Suicide Funding Restriction Act of 1997, it was the policy of the Federal Government not to recognize physician-assisted suicide as a legitimate medical practice. As Acting Solicitor General Walter Dellinger noted in 1996 in the United States Brief in *Glucksberg*:

> The United States owns and operates numerous health care facilities which . . . do not permit physicians to assist patients in committing suicide by providing lethal dosages of medication. The Department of Veterans Affairs (VA), which operates 173 medical centers, 126 nursing homes, and 55 in-patient hospices, has a policy manual that . . . forbids "the active hastening of the moment of death." . . . The military services, which operate 124 centers, the Indian Health service, which operates 43 hospitals, and the National Institutes of Health, which operate a clinical center, follow a similar practice. . . . No federal law . . . either authorizes or accommodates physician assisted suicide.[14]

Other Federal agencies have taken similar views in the past. The Hyde Letter noted that "[t]he Health Care Financing Administration has stated that

[14] Brief for the United States as *Amicus Curiae* Supporting Petitioners at 1-2, *Washington v. Glucksberg*, 521 U.S. 702 (1997) (No. 96-110) (United States Brief in *Glucksberg*).

physician-assisted suicide is not 'reasonable and necessary' to the diagnosis and treatment of disease or injury and is therefore barred from reimbursement under Medicare." Hyde Letter, *supra* note 4, at 1. Administrator Constantine's reply stated that a review of "a number of cases, briefs, law review articles and state laws relating to physician-assisted suicide" and "a thorough review of prior administrative cases in which physicians have dispensed controlled substances for other than a 'legitimate medical purpose'" demonstrated "that delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose.'"[15]

Finally, Federal medical policy *since* the enactment of the Assisted Suicide Funding Restriction Act also supports the conclusion that physician-assisted suicide is not a legitimate medical practice. In 1999, the Surgeon General sought to classify suicide as a serious public health problem and to intensify suicide prevention efforts, especially among high risk groups such as the sick and elderly, who often suffer from un-

[15] Constantine Letter, *supra* note 5, at 1-2. Also relevant to the past practice of Federal agencies is *United States v. Rutherford*, 442 U.S. 544 (1979), which involved a challenge by terminally ill cancer patients to the determination of the Food and Drug Administration (FDA) that Leatrile constituted a "new drug" for purposes of the Federal Food, Drug and Cosmetic Act because it was not generally regarded as safe or effective. In upholding the FDA's determination, the Court rejected the plaintiffs' argument that an implied exception from the Act was justified because the safety and effectiveness standards could have no reasonable application to terminally ill patients. It pointed out that "the FDA has never made exception [from the FDA's safety standards] for drugs used by the terminally ill." *Id.* at 553.

diagnosed depression and inadequately treated pain.[16] Dispensing controlled substances to assist the suicides of some of the most vulnerable members of American society is manifestly inconsistent with the Surgeon General's policy.[17]

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[16] *See generally The Surgeon General's Call To Action To Prevent Suicide (1999)*, Dep't of Health and Human Services, U. S. Public Health Service, http://www.surgeongeneral.gov/library/calltoaction/calltoaction.htm; *see also* Kathleen M. Foley & Hellen Gelbard (eds.), *Improving Palliative Care for Cancer: Summary and Recommendations* (2001) (finding depression common among terminally ill cancer patients, and recommending greater emphasis on palliative care).

[17] *See* United States Brief in *Glucksberg* at 19. Medical evidence suggests that many terminally ill patients who seek death do so not as a result of rational deliberation, but rather because of depression or mental illness. Moreover, given modern palliative care techniques, pain-avoidance cannot justify the general practice of assisted suicide. *See* Susan R. Martyn and Henry J. Bourguignon, *Now Is The Moment to Reflect: Two Years of Experience With Oregon's Physician-Assisted Suicide Law*, 8 Elder L. J. 1, 14-16 (2000) (footnotes omitted) ("First, the rate of depression among terminally ill patients appears to be 'much higher than would be expected in the general population.' Recent studies indicate that fully two-thirds of those requesting assisted suicide suffer from depression. Second, seriously ill patients often require powerful medications which can distort the patient's thoughts and feelings. 'For many patients, the progression of disease will result in the impairment of decisionmaking capacity, either from the effects of the disease itself or those of drug treatment.' Third, seriously ill patients may also suffer physical and mental disability, have short attention spans, or find it difficult to concentrate. They may have difficulty hearing or thinking through complex subjects. . . . Physicians, psychiatrists, and psychologists, like anyone else who deals with a seriously ill, mentally or physically disabled patient can all too easily conclude that the patient's request for assisted suicide is reasonable and therefore competent. The greatest threat is that persons with mental or physical disabilities or depression,

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especially those who burden others, will readily be found competent to request assistance in suicide. . . . Depression, the major precursor of suicidal intent, often worms its way into serious illnesses and, especially among the elderly, can remain undiagnosed and untreated. In fact, clinical studies now indicate that depression is the only factor that predicts suicidal intent or ideation. Indeed, Oregon physicians report that they recognized symptoms of depression in twenty percent of patients who sought suicide assistance."); *id.* at 38-43 (describing significant recent innovations in palliative care, noting that States are increasingly enacting intractable pain legislation to assure physicians that adequate pain control is legally and medically required, and suggesting that legalizing physician-assisted suicide may inhibit advances in such care); New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 11, 13 (1994) ("Studies that examine the psychological background of individuals who kill themselves show that 95 percent have a diagnosable mental disorder at the time of death. Depression, accompanied by symptoms of hopelessness and helplessness, is the most prevalent condition among individuals who commit suicide. . . . In one study of terminally ill patients, of those who expressed a wish to die, all met diagnostic criteria for major depression."); Brief of *Amici Curiae* American Geriatrics Soc. Urging Reversal of the Judgments Below in *Vacco v. Quill*, 521 U.S. 793 (1997) and *Washington v. Glucksberg*, 521 U.S. 702 (1997) (Nos. 95-1858 & 96-100) (1996) (hospice and palliative care programs relieve pain and other severe symptoms for those near death and should be preferred treatment options; also noting high correlation between cognitive or emotional dysfunctioning such as depression and suicide inquiries); Leon R. Kass and Nelson Lund, *Physician-Assisted Suicide, Medical Ethics and the Future of the Medical Profession*, 35 Duq. L. Rev. 395, 406 (1996) ("Because the quick-fix of suicide is easy and cheap, it will in many cases replace the use of hospice and other humanly-engaged forms of palliative care, for there will be much less economic incentive to continue building and supporting social and institutional arrangements for giving humane care to the dying."); Yale Kamisar, *Against Assisted Suicide—Even a Very Limited Form*, 72 U. Detroit Mercy L. Rev. 735, 744 (1995) ("Although pain is notoriously undertreated in this country, 'according to experts in the field of

C. *Views of the Medical and Nursing Professions*

The leading organizations of the American medical profession have repeatedly, and recently, expressed the profession's condemnation of physician-assisted suicide. The American Medical Association (AMA), joined by the American Nurses Association (ANA), the American Psychiatric Association, and 43 other national medical organizations, filed a brief in the *Glucksberg* case declaring that "[t]he ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics" and that physician-assisted suicide is "'fundamentally incompatible with the physician's role as healer.'"[18] More specifically, the AMA's Brief said:

> The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides both medicine and nursing. It is a power that most physicians and nurses do not want and could not control. Once established, the right to physician-assisted suicide would create profound danger for many ill persons with undiagnosed depression and inadequately treated pain, for whom physician-assisted suicide rather than good palliative care could become the norm. At greatest risk would be those with the least access to palliative care—the poor, the elderly, and members of minority groups.

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pain control, almost all terminally ill patients can experience adequate relief with currently available treatments.'") (footnotes omitted); Gorsuch, *supra*, at 691.

[18] Brief of *Amici Curiae* American Medical Association et al. at 5, *Washington v. Glucksberg*, 521 U.S. 702 (1997) (No. 96-110) (1996).

Amici acknowledge that many patients today do not receive proper treatment for their pain, depression, and psychological distress. Nevertheless, physician-assisted suicide is not the right answer to the problem of inadequate care. Although for some patients it might appear compassionate intentionally to cause death, institutionalizing physician-assisted suicide as a medical treatment would put many more patients at serious risk for unwanted and unnecessary death.

. . .

The ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics. Its roots are as ancient as the Hippocratic oath that a physician "will neither give a deadly drug to anybody if asked for it, nor . . . make a suggestion to this effect," and the merits of the ban have been debated repeatedly in this nation since the late nineteenth century. Most recently, the AMA has reexamined and reaffirmed the ethical prohibition against physician-assisted suicide in 1977, 1988, 1991, 1993, and 1996.[19]

As the Court noted in *Glucksberg*, 521 U.S. at 731, the AMA's Code of Ethics condemns physician-assisted suicide as fundamentally incompatible with the physician's role as a healer. AMA, *Code of Ethics* § 2.211 (1994); *see also* Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992). Largely on the basis of the AMA's position, the Court found that the State of Washington had "an interest in protecting the integrity and ethics of the

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[19] *Id.* at 2-5.

medical profession" when it prohibited physician-assisted suicide. *Glucksberg*, 521 U.S. at 731; *see also Compassion in Dying*, 49 F.3d at 592 (citation omitted) ("From the Hippocratic Oath with its promise 'to do no harm,' . . . to the AMA's code, the ethics of the medical profession have proscribed killing.").

The AMA took the same unequivocal position in hearings before Congress on the subject of assisted suicide. *See Assisted Suicide in the United States*: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, United States House of Representatives, 104th Cong., 309-11 (1996) (statement of Lonnie L. Bristow, M.D., Pres., AMA) (1996 Hearing). Dr. Bristow testified:

> The AMA believes that physician-assisted suicide is unethical and fundamentally inconsistent with the pledge physicians make to devote themselves to healing and to life. . . . AMA takes seriously its role as a leader in issues of medical and professional ethics. The AMA's "code of ethics" serves as the profession's defining document as to what is right versus what is wrong in medical practice, and such issues are critical to our professionalism and our role as healers. My primary obligation as a physician is to first be an advocate for my patient. If my patient in understandably apprehensive or afraid of his or her own mortality, I need to provide information, support, and comfort, not help them avoid the issues of death.

Id. at 310.

The ANA, a national organization representing 2.2 million registered nurses, submitted written testimony to Congress at the same hearing. *See id.* at 438-50.

Included in the ANA's submission was the organization's *Position Statement on Assisted Suicide* (1994). The *Position Statement* succinctly summarizes the ANA's view of nurse-assisted suicide as follows:

> The American Nurses Association (ANA) believes that the nurse should not participate in assisted suicide. Such an act is in violation of the *Code for Nurses with Interpretive Statements (Code for Nurses)* and the ethical traditions of the profession.

Id. at 443. The "Rationale" in the *Position Statement* sets forth comprehensively the basis of the ANA's view. It states in part:

> • The profession of nursing is built upon the Hippocratic tradition "do no harm" and an ethic of moral opposition to killing another human being. The ethical framework of the profession as articulated through the *Code for Nurses* explicitly prohibits deliberately terminating the life of any human being.
>
> • Nursing has a social contract with society that is based on trust and therefore patients must be able to trust that nurses will not actively take human life. . . . Nurse participation in assisted suicide is incongruent with the accepted norms and fundamental attributes of the profession. . . .
>
> • While there may be individual patient cases that are compelling, there is high potential for abuses with assisted suicide, particularly with vulnerable populations such as the elderly, poor and disabled. These conceivable abuses are even more

> probable in a time of declining resources. The availability of assisted suicide could forseeably weaken the goal of providing quality care for the dying.

Id. at 445.

Scholars have observed that the norms of the medical and nursing professions with respect to physician-assisted suicide, which reflect the experience and the reflection of centuries, are more compelling now than ever. *See* Kass & Lund, *supra* note 17, at 423 ("Given the great pressures threatening medical ethics today —including, among other factors, a more impersonal practice of medicine, the absence of a lifelong relationship with a physician, the push toward managed care, and the financially-based limitation of services—a bright line rule regarding medically-assisted suicide is a bulwark against disaster."); *see also* Seth F. Kreimer, *Does Pro-Choice Mean Pro-Kevorkian? An Essay on Roe, Casey, and the Right to Die*, 44 Am. U. L. Rev. 803, 841 (1995) ("Particularly with the emergence of cost controls and managed care in the United States, the danger of tempting health care providers to persuade chronic patients to minimize costs by ending it all painlessly is no fantasy.").

To be sure, it has been claimed that physician-assisted suicide has become a common, if also usually clandestine, practice.[20] But the claim is questionable. The American Geriatrics Society, for example, has stated that the Society's leadership "is unfamiliar with situations in which this is true, and it seems unlikely. Three-quarters of all deaths happen in institutions where a regularized endeavor would require the collusion of a large number of persons, which seems implau-

[20] *See, e.g., Compassion in Dying*, 79 F.3d at 811.

sible. Little reliable evidence characterizes the rate and nature of actual instances of [physician-assisted suicide]." Brief of *Amici Curiae* the American Geriatrics Soc., in *Glucksberg*, *supra* note 17, at 10. Moreover, even if there were reliable evidence that unacknowledged physician-assisted suicide was not infrequent, that fact would hardly invalidate the *normative* judgments of the AMA and other medical groups that emphatically condemn the practice. By parity of reasoning, if it could be shown that physicians violated traditional medical canons of ethics more often that is usually supposed, *e.g.*, by engaging in sexual relations with their patients or disclosing patient confidences, it would follow that the evidence of such deviations overturned the professional standards prohibiting such misconduct.

Thus, the overwhelming weight of authority in judicial decisions, the past and present policies of nearly all of the States and of the Federal Government, and the clear, firm and unequivocal views of the leading associations within the American medical and nursing professions, establish that assisting in suicide is not an activity undertaken in the course of professional medical practice and is not a legitimate medical purpose. Indeed, we think it fair to say that physician-assisted suicide should not be considered a *medical* procedure at all. Here we follow an *amicus* brief filed in *Glucksberg* by a group of fifty bioethics professors, who declared that physician-assisted suicide "is not a medical procedure, and medicalizing an act runs the risk of making an otherwise unacceptable act appear acceptable." Brief for Bioethics Professors, *Amici Curiae* Supporting Petitioners, *Vacco v. Quill* & *Washington v. Glucksberg* (Nos. 95-1858 & 96-100) (1996), at 15. As

this brief points out, assisted suicide does not require any medical knowledge whatever, nor does it necessarily depend on access to any prescribed drugs or to medical services. Indeed, the country's most prominent partisan of assisted suicide, Jack Kevorkian, has often used the entirely non-medical method of carbon monoxide poisoning. *See* George J. Annas, *Physician Assisted Suicide—Michigan's Temporary Solution*, 20 Ohio N.U.L. Rev. 561, 568 (1994). It is plainly a fallacy to assume that a procedure must be "medical" because it is performed by a physician rather than, say, by a family member, or because it involves the use of a drug that a physician has prescribed.[21]

Accordingly, we conclude that assisting in suicide is not a "legitimate medical purpose" that would justify a physician's dispensing controlled substances consistent with the CSA.

III. *The Existence of a State Law Permitting Physician-Assisted Suicide Does Not Immunize a Physician from the General Requirements of the CSA*

The CSA establishes a uniform, nation-wide statutory scheme for regulating the distribution of controlled substances. Notwithstanding the traditional role of the

[21] The Oregon Deputy Attorney General's Letter assumes, uncritically, that physician-assisted suicide, if authorized by state law, *must* be considered a "medical" practice that serves a "medical" purpose. *See* Oregon Deputy Attorney General Letter, *supra* note 6, at 7 ("[T]he CSA is addressed to the problems of the abuse and trafficking of controlled substances, [not to] regulating medical practices that are legal under state law and that have no relation to drug abuse or trafficking"). As we have argued above, it is far from obvious (to say no more) that assisting an individual to kill himself or herself *must* be considered a "medical" procedure.

States in regulating the practice of medicine,[22] state law cannot abrogate the CSA or supersede its provisions in the event of conflict.[23] Thus, the fact that assisting in suicide may be permitted in some cases for Oregon physicians under local law does not entail that they should be held immune from criminal prosecution or adverse administrative action under the CSA if they dispense a controlled substance when rendering that assistance. It is simply wrong to suggest, as the Deputy Attorney General of Oregon did, that the CSA does not reach "practices that are engaged in by physicians in accordance with state law."[24]

The Supreme Court's very recent decision in the so-called "medical marijuana" case, *United States v. Oakland Cannabis Buyers' Coop.*, 121 S. Ct. 1711(2001), demonstrates the fallacy of attempting to read an implied immunity into the CSA for physicians who dispense controlled substances to assist suicides in a State in which such conduct is consistent with local law. In *Oakland Cannabis Buyers'*, the Supreme Court addressed the question whether there was an implied "medical necessity" exception to the CSA's general prohibition in 21 U.S.C. § 841(a)(1) on manufacturing and distributing marijuana. Marijuana is a "schedule I" controlled substance. For drugs on that schedule, there is but one express statutory exception, and that exception is available only for Government-approved research projects. *See* 21 U.S.C. § 823(f); *Oakland*

[22] *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012, 1017 (2001); *Gade v. Nat'l Solid Wastes Management Ass'n*, 505 U.S. 88, 108 (1992).

[23] *See, e.g., Rosenberg*, 515 F.2d at 198, n.14.

[24] *See* Oregon Deputy Attorney General Letter, *supra* note 6, at 6.

Cannabis Buyers', 121 S. Ct. at 1714.[25] Notwithstanding the fact that it did not fall within the sole express statutory exception, the defendant Cooperative argued that the statute should be read to include another, implied exception for "medical necessity." The Supreme Court refused to read such an exception into the CSA.

Because of the passage in a 1996 voter initiative of the Compassionate Use Act of 1996, Cal. Health & Safety Code Ann. § 11362.5 (West Supp. 2001), California laws prohibiting the possession and cultivation of marijuana now include an exception for a patient or primary caregiver who possesses or cultivates marijuana for the patient's medical purposes upon the recommendation or approval of a physician. In the wake of the voter initiative, "medical cannabis dispensaries" were organized to meet the needs of qualified patients. The defendant was one such organization, and distributed marijuana to those it accepted as members. The United States sued the defendant in 1998, arguing that, "whether or not the Cooperative's activities are legal under California law, they violate" § 841(a) of the CSA. *Oakland Cannabis Buyers'*, 121 S. Ct. at 1716. Despite being enjoined from distributing marijuana, the defendant continued to do so, and the United States accordingly initiated contempt proceedings. In defense,

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[25] The controlled substances usually used in physician-assisted suicide are, as we have noted, schedule II substances, and accordingly are governed by a different regulatory régime from schedule I substances. In particular, registered practitioners may "dispense" schedule II, but not schedule I, substances. *See* 21 U.S.C. § 824(f). This distinction does not, however, affect the relevance of *Oakland Cannabis Buyers'* to the questions considered in this memorandum.

it was "contended that any distributions were medically necessary. Marijuana is the only drug, according to the Cooperative, that can alleviate the severe pain and other debilitating symptoms of the Cooperative's patients." *Id.* (citation omitted). The district court found the defendant in contempt, and declined to modify its injunction so as to permit marijuana distributions that were asserted to be medically necessary. Although the defendant's appeal of the contempt order was mooted, its motion to modify the injunction presented a live controversy, and the court of appeals accepted the defendant's argument that medical necessity was a legally cognizable defense under the CSA. The United States sought certiorari to review the court of appeals' decision, and the Supreme Court granted the petition because the appellate decision below "raise[d] significant questions as to the ability of the United States to enforce the Nation's drug laws." *Id.* at 1717.

The Supreme Court flatly rejected the defendant's claim of an implied medical necessity exception. "[T]o resolve the question presented, we need only recognize that a medical necessity exception for marijuana is at odds with the terms of the Controlled Substances Act. The statute, to be sure, does not explicitly abrogate the defense. But its provisions leave no doubt that the defense is unavailable." *Id.* at 1718 (footnote omitted).

The question whether Oregon physicians may dispense controlled substances to assist in a suicide without violating the CSA is similar to (although it is of course not the same as) the question decided in *Oakland Cannabis Buyers'*. In effect, the argument that such physicians do *not* violate the CSA depends on the assumption that because assisting suicide in that manner is permissible under state law, the CSA must

be interpreted so that such dispensing is done "in the course of professional practice," 21 U.S.C. § 802(21), and the DEA's regulations must be read so that such actions serve "a legitimate medical purpose," 21 C.F.R. § 1306.04(a). But a State cannot, by its unilateral action, take its physicians' conduct out of the scope of otherwise nationally applicable prohibitions on the dispensing of controlled substances. The CSA contains no express immunity for such conduct in States in which physicians may assist suicides compatibly with local law, and it should not be construed in a manner that implies such an immunity.[26]

IV. *The CSA Contemplates Concurrent Federal and State Regulation of Medical Practices Involving Controlled Substances*

Like the Court in *Oakland Cannabis Buyers'*, we share the concern for "'showing respect for the sovereign States that comprise our Federal Union.'" *Oakland Cannabis Buyers'*, 121 S. Ct. at 1720, n.7 (quoting Stevens, J., concurring in judgment). But we think it shows no disrespect for the principles of federalism to conclude that the States cannot, by their unilateral

[26] We note that the 1998 Letter, *see supra* note 7, at 3-4, expressly recognized that its conclusion was "limited to these particular circumstances" in Oregon (and, should any other State follow Oregon, such a State), and affirmed that "[a]dverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions." Construing the CSA and its regulations as Attorney General Reno did would accordingly cause the Act's prohibitions to apply differently from one State to another, and would in effect grant the States the power to immunize their physicians from liability under otherwise generally applicable Federal law.

actions, shelter their physicians from the Federal narcotics code. Although the States are the *primary* regulators of the practice of medicine, they are not its *exclusive* regulators: since the Harrison Narcotics Act of 1914, the Federal Government has regulated the practice of medicine insofar as it involved the dispensing of controlled drugs.[27] Physicians were often prosecuted under the Harrison Act for prescribing drugs in a manner that did not comport with Federal statutory requirements or that fell outside the course of professional practice as determined by the Federal courts.[28] Further, the Supreme Court repeatedly upheld the authority of Federal prosecutors to bring such cases against physicians over the objection that the Harrison Act impermissibly encroached on a regulatory

[27] *See Moore*, 423 U.S. at 132 ("Physicians who stepped outside the bounds of professional practice could be prosecuted under the Harrison Act (Narcotics) of 1914, 38 Stat. 785, the predecessor of the CSA."); *id.* at 139 ("Under the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy.").

[28] *See, e.g., United States v. Behrman*, 258 U.S. 280 (1922) (sustaining conviction of physician over dissent's argument that defendant should have been assumed to have given drugs in the regular course of his practice and in good faith); *Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920) (sustaining conviction; Court states that "[m]anifestly the phrases 'to a patient' and 'in the course of his professional practice only' are intended to confine the immunity of a registered physician, in dispensing the narcotic drugs mentioned in the act, strictly within the appropriate bounds of a physician's . . . practice."); *Webb v. United States*, 249 U.S. 96, 99-100 (1919) (holding that to call the defendant's order for the use of morphine a "physician's prescription" would "be so plain a perversion of meaning that no discussion of the subject is required.").

power exclusively reserved to the States.[29] The CSA was intended "to strengthen rather than to weaken the prior drug laws."[30] Consequently, dispensing controlled substances has been an aspect of medical practice that the Federal Government has regulated concurrently with the States for some eighty-seven years.[31]

Both in enacting the CSA in 1970 and in amending it in 1984, Congress was well aware that enforcement of the Federal law would unavoidably necessitate Federal regulation of medicine concurrent with, and in some circumstances designedly superseding, state regulation. In the House Report on what is now 42 U.S.C. § 257a,[32] the Committee on Interstate and Foreign Commerce noted the difficulty but found it inescapable:

> Although the committee is concerned about the appropriateness of having Federal officials determine the appropriate method of the practice of

[29] *See Nigro v. United States*, 276 U.S. 332, 353-54 (1928) (upholding constitutionality of Harrison Act as revenue measure despite claim that it infringed on States' police power to regulate intrastate purchases of commodities); *Linder v. United States*, 268 U.S. 5, 18 (1925) (prosecution of physician under Harrison Act; Court states that while "direct control of medical practice in the States is beyond the power of the Federal Government," "[i]ncidental regulation of such practice by Congress through a taxing act" may be permitted); *United States v. Doremus*, 249 U.S. 86, 93-94 (1919).

[30] *Moore*, 423 U.S. at 139.

[31] *Cf. Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41 (1921) (state law regulating physicians' furnishing or prescribing narcotic drugs held compatible with Harrison Act).

[32] This provision was originally enacted as § 4 of title I of the Comprehensive Drug Abuse and Control Act of 1970, 84 Stat. 1236, 1241 (1970); title II comprised the CSA. Hence the legislative history of the provision is highly relevant to the CSA.

> medicine, *it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinion of Federal prosecutors of what constitutes appropriate methods of professional practice.*

H.R. Rep. No. 91-1444, pt. 1, 91st Cong. at 15 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4581 (emphasis added).

Further, Congress revisited the CSA in 1984 in order to add amendments that expanded Federal authority at the expense of the States and were specifically directed against the misuse of Federally regulated prescription drugs (that otherwise have legitimate medical uses) in a manner that did not violate state law. The expanded Federal authority was accomplished by adding "inconsistency with the public interest" as a ground for denying, suspending, or revoking Federal registration. *See* 21 U.S.C. § 823(f) ("The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest.") and *id.* § 824(a)(4) (DEA may revoke registration of any physician who has committed acts "inconsistent with the public interest."). Previously, the Federal Government lacked the authority under the CSA to deny a physician's registration application when the physician possessed a license from the State to practice medicine and had no felony drug conviction. *See* S. Rep. No. 98-225, at 262 (1984) (footnote omitted) ("the Attorney General must presently grant a practitioner's registration application unless his State license has been revoked or he has been convicted of a felony drug

offense, even though such action may clearly be contrary to the public interest").[33]

Supporters of the 1984 amendments explained that the most serious threat to "public health and safety" prompting this legal change was the frequency with which prescription drugs were involved in "drug-related deaths" and overdoses that threatened life.[34] Representative Hamilton Fish, a sponsor of the 1984 amendments, said that giving flexibility to the Federal Government was necessary because States often did not respond adequately to abuses: "State policing of these activities . . . have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate." 130 Cong. Rec. at 25,849. At a hearing before the House Commerce Subcomm. on Health and the Environment, the DEA called the expanded Federal authority to revoke practitioner registrations "one of the most important sections of the bill," not only because States were often ill-equipped to enforce their own drug laws but also

[33] *See also* 130 Cong. Rec. 25,852 (1984) (statement of Rep. Rangel); *see generally Moore*, 423 U.S. at 140-41 ("In the case of a physician th[e] scheme [of the registration provision of the then-existing CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice. The federal registration . . . follows automatically.").

[34] *Dangerous Drug Diversion Act of 1984:* Hearing on H.R. 5656 Before House Comm. on Health and the Environment, 98th Cong., 365 (1984) (testimony of Rep. Waxman) ("[d]rugs legally manufactured for use in medicine are responsible for a substantial majority of drug-related deaths and injuries"); *see also* 130 Cong. Rec. 25,851 (statement of Rep. Rodino) ("prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse").

because "[m]any controlled drug violations involving prescription drugs are not felonies under state law and therefore cannot be used in a DEA revocation action" under then-existing law.[35] Members of Congress also explained that the 1984 amendments were intended to "expand[] the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner's own jurisdiction."[36]

Congress intended, therefore, that the "inconsistent with the public interest" standard be more demanding than the standard of a physician's licensing State. The 1984 amendments authorized the DEA to enforce the CSA against medical practitioners who prescribed controlled substances in a manner that "endangers public health or safety" contrary to the "public interest," notwithstanding the nature or content of state law or regulation. Consistent with Congress' purpose, the public interest standard incorporated in § 824(f) is best understood to authorize suspension or revocation of the Federal registration of a practitioner who dispenses controlled substances to assist in a suicide, even if such conduct is permitted under state law.

V. *The CSA's Preemption Provision Is Consistent With This Interpretation*

The CSA itself includes a provision designed to narrow possible Federal preemption of state law. The

[35] *Dangerous Drug Diversion Control Act of 1984*: Hearing on H.R. 5656 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 403-04 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

[36] 130 Cong. Rec. 1,586 (1984) (statement of Sen. Laxalt); *see also* 130 Cong. Rec. at 25,851-52 (statement of Rep. Rangel).

provision is found at 21 U.S.C. § 903. Section 903 plainly does not require the Department of Justice to accept Oregon's determination of what is a "legitimate medical purpose."

Section 903 reads as follows:

> **Application of State law**
>
> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903.

For at least two reasons, we do not think that § 903 affects the conclusion that assisting in a suicide is not a legitimate medical purpose that would justify a physician's dispensing a controlled substance.

First, if § 841(a) and other pertinent parts of the CSA are read and applied in accordance with the DEA's regulation, 21 C.F.R. § 1306.04(a), and the interpretation of it here, it would certainly not follow that the CSA was being understood to "occupy the field" of regulating the medical profession to the "exclusion of any State law."[37] On the contrary, as we have just

[37] Congress' intent to preempt all state law in a particular area may be inferred "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation" or "where the field is one in which 'the federal interest is so dominant

shown, the States remain free to regulate that profession *concurrently* with the Federal government, as they have done since 1914. Federal regulation of the profession under the CSA would reach only the dispensing of controlled substances, which is hardly the whole field of medical practice. Moreover, States would remain free to regulate that activity as well, as long as such regulation did not conflict with Federal law.

Second, even if our interpretation would make it harder as a practical matter for Oregon physicians to assist in suicides, the CSA and its regulations as we read them do not *preempt* Oregon's Death With Dignity Act.[38] Oregon physicians remain free under that law to assist in suicides, provided of course that they follow the procedures that Oregon imposes. All that our interpretation does is to affirm that *dispensing controlled substances in connection with such an assisted suicide* will cause an Oregon physician to be in violation of the CSA. Any method of assisting in suicides in which an Oregon physician does *not* dispense a controlled substance entails *no* violation of the CSA. The Attorney General's interpretation forecloses one, but

that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 713 (1985) (citations omitted). Interpreting the CSA and its regulations to reach the conduct of physicians who dispense drugs to assist suicide does not require the assumption that Congress intended to occupy the field of regulation of the medical profession.

[38] *Cf. Dalton v. Little Rock Family Planning Servs.*, 516 U.S. 474, 476 (1996) (per curiam) (state law preempted only to the extent that it "'actually conflicts'" with federal law) (citation omitted); *Pharmaceutical Society of State of New York v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (no preemption because no actual conflict).

only one, method of assisting suicide in a manner consistent with Oregon law.

We respectfully disagree with the contrary opinion of the Oregon Deputy Attorney General. *See* Oregon Deputy Attorney General Letter, *supra* note 6, at 7-8. That Letter argues, in part, that the CSA should not be construed to enable the Attorney General to regulate the practice of medicine, which is said to be an area traditionally reserved to the States. We consider that argument to be mistaken.

First, as we have shown, the Federal Government has regulated the dispensing of controlled substances by physicians continuously since the Harrison Act of 1914, and in enacting the CSA in 1970, Congress clearly intended that the Attorney General continue to do so.[39]

Second, as we have also shown, the legislative history of the 1984 amendments to the CSA demonstrates that Congress intended the Attorney General to have regulatory authority with respect to the conduct of physicians even in circumstances in which that conduct was not sanctionable under state law.

Third, the activity of assisting in suicide should not, in our view, be considered a "medical" practice solely because it is undertaken by a physician: as we have shown, physician-assisted suicide has been condemned by the overwhelming majority of the States and by the leading professional associations of medical and nursing practitioners. On the theory of the Oregon Deputy Attorney General's Letter, an act that was performed by doctors, despite being forbidden by ordinary professional standards or even punishable elsewhere as a

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[39] *See Moore*, 423 U.S. at 132-33.

crime, could be transformed into a "medical" practice if a single State were to decide to deem it so; and that State's unilateral decision would presumptively place the act beyond the reach of Federal regulation. It would follow that if a State authorized physicians to perform involuntary euthanasia on severely handicapped or mentally retarded persons, and thus "medicalized" that procedure, it could place it beyond Federal regulatory power pursuant to the CSA even if controlled substances were used. Equally, it would follow that if a State authorized physicians to prescribe controlled substances to addicts in order to enable them to maintain their customary use and so avoid discomfort, the Federal Government would be unable to prosecute those physicians or to revoke their registrations under the CSA. We cannot accept these consequences of the theory: no State has the power to determine unilaterally what practices count as "medical" for purposes of the CSA.

VI. *The DEA Had the Authority to Promulgate and Interpret A Regulation Concerning Whether Dispensing a Controlled Substance Has a "Legitimate Medical Purpose"*

Finally, we consider the basis of the Attorney General's authority to determine that dispensing a controlled substance to assist in a suicide in a State permits such conduct on the part of a physician does not serve a "legitimate medical purpose" under 21 C.F.R. §1306.04 (a).

We address this question because of an apparent ambiguity in the 1998 Letter. The Letter could be understood, not as controverting DEA's interpretation of the CSA and the DEA's own regulations, but rather

as making the *jurisdictional* claim that DEA lacked statutory authority to find that a physician's prescription of controlled substances to assist a suicide in Oregon went beyond "the course of professional practice," 21 U.S.C. § 802(21), and did not serve a "legitimate medical purpose," 21 C.F.R. § 1306.04(a). *See* 1998 Letter, *supra* note 7, at 3 ("[T]here is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving 'the earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide.' *Washington v. Glucksberg*, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances."). We do not understand the 1998 Letter to be making a jurisdictional point. but rather to be offering its own interpretation of the CSA and the DEA's regulations. If, however, the Letter were understood to be putting forward a jurisdictional claim, we think that it would be both misleading and mistaken.

First, it is misleading to raise the question whether Congress assigned responsibility for interpreting and enforcing the CSA to *the DEA*. It is clear that Congress assigned that responsibility to *the Attorney General*, not to the DEA. *See* 21 U.S.C. § 821 ("*The Attorney General* is authorized to promulgate rules and regulations . . . relating to the . . . dispensing of controlled substances . . . and control of regulated persons and of regulated transactions") (emphasis added); *id.*, § 871(b) ("*The Attorney General* may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.") (emphasis added). The Attorney General is authorized to delegate his or her CSA responsibilities

to "any officer or employee of the Department of Justice," *id.*, § 871(a), and the Attorney General determined to delegate those functions to the DEA. *See Touby*, 500 U.S. at 169. Thus, if the 1998 Letter were construed to be questioning the DEA's authority to interpret, *e.g.*, what the CSA means by "the course of professional practice," 21 U.S.C. § 802(21), it would necessarily be questioning the authority of *the Attorney General* to interpret that provision. Such a conclusion would plainly be at odds with the broad language of the CSA's authorizing provisions, *id.*, §§ 821, 871(b).

Second, it is also misleading to say that Congress did not intend to assign to the DEA the role of resolving the national debate over physician-assisted suicide. Of course Congress did not intend to do that. What Congress plainly *did* intend to do was to give the Attorney General (and, accordingly, his or her delegate, the DEA) the authority to "promulgate rules and regulations . . . relating to the . . . dispensing of controlled substances and control of regulated persons." *Id.*, § 821. That is precisely what the DEA did when it promulgated a regulation such as 21 C.F.R. § 1306.04(a); and it was well within the scope of DEA's authority to determine how that regulation was to be applied to the use of controlled substances in physician-assisted suicides.

Third, the DEA did not undertake to "*resolve*" the national debate over physician-assisted suicide, and should not be faulted for having attempted to do so. The DEA acts pursuant to delegated authority under an Act of Congress. Congress remains free to alter the terms on which the DEA acts: it could, *e.g.*, carve out an exception for the use of controlled substances by physicians to assist suicide. Moreover, the DEA has no

power to control the ability of the States to enact laws permitting (or forbidding) physician-assisted suicide. What DEA could, and did, properly resolve was that the dispensing of controlled substances by a physician to assist a suicide did not have a "legitimate medical purpose" within the meaning of its own regulation, notwithstanding the fact that a single State chose to legalize physician-assisted suicide. In *no* way did the DEA preclude open and vigorous debate in the legislative process on the merits of physician-assisted suicide.

Fourth, the 1998 Letter suggests that the DEA—and, by necessary implication, the Attorney General—had no authority to adopt an interpretation that addressed "fundamental questions of morality and public policy." 1998 Letter at 3. If that were so, it would follow that the Attorney General had no authority to decide whether dispensing controlled substances to assist in suicide served a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a), because in deciding that question—one way or the other—the Attorney General would unavoidably be addressing such moral and policy questions.[40] Indeed, it seem to would follow that that regulation was itself *ultra vires*—which is clearly a mistaken view.

The truth is that, far from being outside the Attorney General's mission under the CSA, addressing such questions is inherent in that mission. *See Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984) ("The power of an administrative agency to administer a congressionally created program neces-

[40] We note that the 1998 Letter was *itself* an administrative interpretation that assumed a particular view of public policy.

sarily requires the formulation of policy . . ") (internal quotation marks, internal ellipses and citation omitted). If the CSA is to be administered effectively, the Attorney General *must* interpret its provisions so as to decide, *e.g.*, whether prescribing of controlled substances in a particular class of cases takes place within the "course of professional practice," 21 U.S.C. § 802(21), whether a physician's conduct involving such substances "may threaten the public health and safety," *id.*, § 823(f)(5), and whether issuing a registration to an applicant would be "inconsistent with the public interest," *id.*, § 823(f). Of course such administrative determinations will require a judgment about public policy.[41] So do, *e.g.*, administrative determinations as to what constitute "excessive profits" on government contracts, *see Lichter v. United States*, 334 U.S. 742, 778-86 (1948), when commodity prices are "fair and equitable," *see Yakus v. United States*, 321 U.S. 414, 426-27 (1944), when rates for the sale of a commodity are "just and reasonable," *see Federal Power Comm'n v. Hope Gas Co.*, 320 U.S. 591, 600-02 (1944), when voting power has been "unfairly or inequitably" distributed among security holders, *see American Power & Light Co. v. SEC*, 329 U.S. 90, 104 (1946), when broadcast licensing is in the "public interest," *see National Broadcasting Co. v. United States*, 319 U.S. 190, 225-26 (1943), or when a new drug poses an "imminent hazard to the public safety," *see Touby*, 500 U.S. at 165. *See generally Whitman v. American Trucking Ass'n, Inc.*, 121

[41] Indeed, one of the primary reasons why an agency's construction of a statute it administers may be entitled to judicial deference is that it is more appropriate for an agency to make "policy choices" than it is for the courts. *Chevron*, 467 U.S. at 865.

S. Ct. 903, 912 (2001).[42] As a matter of administrative practice, there was nothing unusual or unauthorized in the fact that the DEA's interpretation implicated questions of public policy or morality.

Accordingly, if the 1998 Letter were construed as denying the Attorney General (or the DEA) the statutory authority to reach the question whether prescribing controlled substances to assist suicide is consistent with the CSA and its implementing regulations in a State that had legalized physician-assisted suicide, the Letter would be clearly mistaken as a matter of law.

Conclusion

Based on the foregoing considerations, the conclusion that a physician's assisting suicide through the dispensing of a controlled substance does not serve a "legitimate medical purpose" within the meaning of 21 CFR § 1306.04 is the best reading of that regulation.

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[42] The Department of Justice may also be required to interpret statutes implicating judgments about policy or morality when bringing criminal prosecutions or when instituting deportation proceedings. *See, e.g., Jordan v. DeGeorge*, 341 U.S. 223, 231 & n.15 (1951) (deportation proceeding based on alien's commission of asserted "crime involving moral turpitude;" Court finds that phrase "presents no greater uncertainty or difficulty than language found in many other statutes repeatedly sanctioned by the Court"); *see also Kay v. United States*, 303 U.S. 1, 3, n.1, 7 (1938) (rejecting argument that statute making it criminal in some contexts willfully to "overvalue[] any security" was unconstitutionally vague).

APPENDIX F

UNITED STATES CODE

TITLE 21—FOOD AND DRUGS

Sec. 801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

* * * * *

Sec. 802. Definitions

As used in this subchapter:

* * * * *

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

* * * * *

Sec. 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

* * * * *

Sec. 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. * * *

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United

States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

* * * * *

Sec. 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions.

Sec. 822. Persons required to register

(a) Period of registration

* * * * *

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized

to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

* * * * *

Sec. 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded there from into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

* * * * *

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

* * * * *

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the

State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of

such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheuled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

* * * * *

Sec. 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State

authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of title 42.

* * * * *

Sec. 829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

* * * * *

Sec. 830. Regulation of listed chemicals and certain machines

* * * * *

(b) Reports to Attorney General

* * * * *

(3) MAIL ORDER REPORTING.—(A) As used in this paragraph:

* * * * *

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by

law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

Sec. 841. Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance;

* * * * *

Sec. 871. Attorney General

* * * * *

(b) Rules and regulations

The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

* * * * *

Sec. 903. Application of State law

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

APPENDIX G

CODE OF FEDERAL REGULATIONS

TITLE 21-FOOD AND DRUGS

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

Sec. 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

* * * * *

APPENDIX H

OREGON REVISED STATUTES

127.800. Definitions.

The following words and phrases, whenever used in ORS 127.800 to 127.897, have the following meanings:

* * * * *

(7) "Informed decision" means a decision by a qualified patient, to request and obtain a prescription to end his or her life in a humane and dignified manner, that is based on an appreciation of the relevant facts and after being fully informed by the attending physician of:

(a) His or her medical diagnosis;

(b) His or her prognosis;

(c) The potential risks associated with taking the medication to be prescribed;

(d) The probable result of taking the medication to be prescribed; and

(e) The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control.

(8) "Medically confirmed" means the medical opinion of the attending physician has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records.

* * * * *

127.805. Who may initiate a written request for medication.

(1) An adult who is capable, is a resident of Oregon, and has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with ORS 127.800 to 127.897.

* * * * *

127.815. Attending physician responsibilities.

(1) The attending physician shall:

(a) Make the initial determination of whether a patient has a terminal disease, is capable, and has made the request voluntarily;

(b) Request that the patient demonstrate Oregon residency pursuant to ORS 127.860;

(c) To ensure that the patient is making an informed decision, inform the patient of:

(A) His or her medical diagnosis;

(B) His or her prognosis;

(C) The potential risks associated with taking the medication to be prescribed;

(D) The probable result of taking the medication to be prescribed; and

(E) The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control;

(d) Refer the patient to a consulting physician for medical confirmation of the diagnosis, and for a determination that the patient is capable and acting voluntarily;

(e) Refer the patient for counseling if appropriate pursuant to ORS 127.825;

(f) Recommend that the patient notify next of kin;

(g) Counsel the patient about the importance of having another person present when the patient takes the medication prescribed pursuant to ORS 127.800 to 127.897 and of not taking the medication in a public place;

(h) Inform the patient that he or she has an opportunity to rescind the request at any time and in any manner, and offer the patient an opportunity to rescind at the end of the 15 day waiting period pursuant to ORS 127.840;

(i) Verify, immediately prior to writing the prescription for medication under ORS 127.800 to 127.897, that the patient is making an informed decision;

(j) Fulfill the medical record documentation requirements of ORS 127.855;

(k) Ensure that all appropriate steps are carried out in accordance with ORS 127.800 to 127.897 prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner; and

(L)(A) Dispense medications directly, including ancillary medications intended to facilitate the desired effect to minimize the patient's discomfort, provided the attending physician is registered as a dispensing physician with the Board of Medical Examiners, has a

current Drug Enforcement Administration certificate and complies with any applicable administrative rule; or

(B) With the patient's written consent:

(i) Contact a pharmacist and inform the pharmacist of the prescription; and

(ii) Deliver the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician or an expressly identified agent of the patient.

(2) Notwithstanding any other provision of law, the attending physician may sign the patient's death certificate.

127.820. Consulting physician confirmation. Before a patient is qualified under ORS 127.800 to 127.897, a consulting physician shall examine the patient and his or her relevant medical records and confirm, in writing, the attending physician's diagnosis that the patient is suffering from a terminal disease, and verify that the patient is capable, is acting voluntarily and has made an informed decision.

* * * * *

127.885. Immunities; basis for prohibiting health care provider from participation; notification; permissible sanctions. Except as provided in ORS 127.890:

(1) No person shall be subject to civil or criminal liability or professional disciplinary action for participating in good faith compliance with ORS 127.800 to 127.897. This includes being present when a qualified patient takes the prescribed medication to end his or her life in a humane and dignified manner.

* * * * *

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IN THE
Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL
OF THE UNITED STATES, *ET AL.*

PETITIONERS,

v.

STATE OF OREGON, *ET AL.*,

RESPONDENTS.

On Petition for Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

BRIEF OF FOCUS ON THE FAMILY AND THE FAMILY RESEARCH COUNCIL AS *AMICI CURIAE*, SUPPORTING PETITIONERS

WILLIAM WAGNER
NELSON P. MILLER
Counsel of Record

COOLEY LAW SCHOOL
300 South Capitol
Lansing, MI 8933
(517) 371-5140

STEPHEN W. REED
35 N. Lake Ave.
Pasadena, CA 91101
(626) 449-4521

PATRICK A. TRUEMAN
801 G. Street NW
Washington D.C. 20001
(202) 393-2100

TABLE OF CONTENTS

TABLE OF AUTHORITIES II

INTEREST OF *AMICI CURIAE* 1

CONSENT TO FILE BRIEF 2

SUMMARY OF ARGUMENT 3

ARGUMENT 4

THE COURT OF APPEALS ERRED IN GRANTING OREGON'S REQUEST TO ENJOIN THE UNITED STATES FROM ENFORCING THE FEDERAL CONTROLLED SUBSTANCES ACT 4

A. The Federal Controlled Substances Act Preempts the Oregon Law Authorizing Physicians to Dispense Drugs to Assist the Killing of a Human Being 4

B. The Attorney General Acted within His Statutory Authority 8

C. Enjoining the United States from Protecting the Citizenry against Dispensing Drugs to Kill a Human Being, Creates a Culture of Death with Grave Implications 14

CONCLUSION 19

TABLE OF AUTHORITIES

Cases:

Boggs v. Boggs, 520 U.S. 833 (1997) 7
Gade v. National Solid Waste Management Assn., 505 U.S. 98 (1992).....7
Hisquierdo v. Hisquierdo, 439 U.S. 572 (1979).....7
United States v. Moore, 423 U.S. 122 (1975).....5,7,9
Washington v. Glucksberg, 521 U.S. 702 (1997).....16
United States v. Steele, 147 F.3d 1316 (11th Cir. 1998)(en banc) (and cases cited therein), cert. denied, *Steele v. United States*, 528 U.S. 933 (1999).....5
Ashcroft v. Oregon, (court of appeals opinion, filed May 26, 2004 -- Pet. App.).....8,13
Oregon v Ashcroft, (district court opinion and order -- Pet. App.).....4,11

Constitution, statutes, and regulations:

U.S. Const. art. VI.....3,6,7,19
Or. Rev. Stat. §§ 127.800 *et seq.* (2003)..3,4,15,17,18,19
Assisted Suicide Funding Restriction Act of 1997, Pub. L. 105-12, Apr. 30, 1997, 111 Stat. 23.....5,6
21 U.S.C. § 802 (10).....11
21 U.S.C. § 802 (21).....5,6,11
21 U.S.C. § 802 (27).....11
21 U.S.C. § 821.....9,12
21 U.S.C. § 822 (a)(2).....9
21 U.S.C. § 822 (b).....9
21 U.S.C. § 823 (f).....9,10
21 U.S.C. § 824(a)(4).....9,10,13
21 U.S.C. § 829.....5,6,11
21 U.S.C. 830 (b)(3)(ii).....12

21 U.S.C. § 841(a) (1).....5,6
21 U.S.C. § 841 (b)(1)(C).....5,7
21 U.S.C. § 871 (b).....9
21 U.S.C. § 885(a)(1).....5
21 U.S.C. 903.....6
21 CFR § 306.04(a) (1973) (re-designated as 21 CFR § 1306.04(a) (1975).....5,6,12
Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg at 56,608).....3,8,13

Miscellaneous:

Sissella Bok, *Physician-Assisted Suicide*, in Euthanasia and Physician-Assisted Suicide 139 (Gerald Dworkin, et al., eds., (1998).....14

Kathleen Foley, and Herbert Hendin, The Case Against Assisted Suicide, For the Right to End-of-Life Care (Foley & Hendin, eds 2002).....8,15,16,17,18

M.D. Reed and J.Y. Greenwald, *Survivor Victim Status, Attachment and Sudden Death Bereavement*, 21 J. of Suicide and Life-Threatening Behavior 385 (1991).....17

Brief of the American Medical Assn., American Nurses Assn., American Psychiatric Assn., et al., as Amicus Curiae in Support of Petitioners at 5, *Glucksberg* (No. 96-110), available in 1996 WL 56263.....18

Memorandum for the Attorney General, (June 27, 2001 -- Pet. App.).....4,11

INTEREST OF AMICI CURIAE

This *amicus curiae* brief is filed on behalf of Focus on the Family and the Family Research Council.[1]

Focus on the Family is a non-profit religious corporation committed to strengthening the emotional, psychological, and spiritual health of children and their families in the United States and throughout the world.

Focus on the Family's Founder and Chairman, Dr. James Dobson, a distinguished child psychologist, is the author of numerous books, pamphlets, and papers on child development, education, marriage, and society. Focus on the Family and Dr. Dobson have been at the forefront of the pro-life movement and have spoken and written extensively concerning individual and societal dangers associated with assisted suicide. Focus on the Family has participated as *amicus curiae* on numerous briefs to this Court and others in cases addressing issues of life. It regularly lobbies Congress and state legislatures concerning matters associated with the sanctity and preservation of life. See: www.family.org

Family Research Council is a non-profit, research and educational organization dedicated to articulating and advancing a family-centered philosophy of public life. FRC is a voice for the pro-family movement in Washington, D.C., and provides policy analysis, legislative assistance, and research for pro-life and pro-family organizations. It also

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[1] In accordance with Supreme Court Rule 37(6), *amici* certify that this brief was authored entirely by Counsel of Record for *amici* and that no part of the brief was authored by any attorney for a party. The Alliance Defense Fund provided a monetary contribution to the preparation or submission of this brief; no other person or entity other than *amici curiae* or their counsel provided a monetary contribution to the preparation or submission of this brief.

seeks to educate legislators on issues that affect American families.

In addition to providing policy research and analysis for the legislative, executive, and judicial branches of the federal government, FRC works to inform the news media, the academic community, business leaders, and the general public about family issues that affect the nation. FRC publishes and disseminates resource materials, legal memoranda, and public policy studies on pro-family issues. These publications include discussions on the problems and legal controversies surrounding assisted suicide. See: www.frc.org. Its research, publications, and films on the impact of assisted suicide have been distributed to thousands of scholars, students, organizations, and citizens. FRC's legal and public policy experts are continually sought out by members of Congress and state legislators for assistance and advice on matters of bioethics and issues relating to assisted suicide.

FRC has participated in numerous *amicus curiae* briefs in the United States Supreme Court and federal courts, including cases involving pro-life issues.

Focus on the Family and Family Research Council work to preserve and protect the family and have particular knowledge about the social and legal impact of assisted suicide that will be helpful to the Court in this case.

CONSENT TO FILE BRIEF

Petitioner and Respondents, through their counsel of record, consented to the filing of this Brief *Amici Curiae* in support of Petitioner. Their letters of consent are on file with the Clerk of the Court.

SUMMARY OF THE ARGUMENT

The issues in this case implicate important federalism concerns vital to proper constitutional governance under the rule of law.

The appellate court's analysis, granting Oregon's request to enjoin the United States from enforcing the Federal Controlled Substances Act (CSA), is incompatible with the Supremacy Clause in Article VI of the United States Constitution. Mutually exclusive provisions of the Federal CSA and Oregon law make it impossible for a dispensing physician to comply with both. In such situations this Court has deemed the state law preempted – even where a distinctive state interest is at stake. See e.g., *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 581 (1979) (finding state community property law preempted by federal military pay law). Thus, even *without considering* the Attorney General's reasonable interpretation of the CSA's implementing regulation, the two statutes here conflict to the extent they cannot consistently stand together.

The Attorney General's interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 136.04. Pet. App. 100a (AG Order no. 2534-2001). When this interpretation of the CSA's implementing regulation is added into the analysis, federal preemption is irrefutable. In promulgating this interpretive rule concerning the dispensing of controlled substances, the Attorney General acted within the scope of his statutory authority.

Amici, therefore, urge this Court to grant the Petition for Certiorari.

ARGUMENT

THE NINTH CIRCUIT ERRED IN GRANTING OREGON'S REQUEST TO ENJOIN THE UNITED STATES FROM ENFORCING THE FEDERAL CONTROLLED SUBSTANCES ACT (CSA)[2]

The issues in this case implicate important federalism concerns vital to proper constitutional governance under the rule of law.

A. THE FEDERAL CONTROLLED SUBSTANCES ACT PREEMPTS THE OREGON LAW AUTHORIZING PHYSICIANS TO DISPENSE DRUGS TO ASSIST THE KILLING OF A HUMAN BEING

The relevant Oregon law in this case authorizes physicians, in certain circumstances, to prescribe and dispense a lethal amount of drugs for the purpose of assisting in the killing of a human being. Or. Rev. Stat. §§ 127.800 *et seq.* (2003). The Oregon law expressly provides that a physician cannot "be subject to civil or criminal liability or professional disciplinary action" for engaging in the conduct authorized by the Oregon law. *Id.* § 127.885 (1)

The drugs dispensed in the lethal conduct authorized by the Oregon law are controlled substances regulated under the Federal CSA. Pet. App. 114a (Memorandum for the Attorney General, June 27, 2001). Generally, such substances are among those listed in Schedule II of the CSA. *Id.;* see also Pet. App. 65a (opinion of the district court).

The conduct authorized as legitimate and immune from prosecution in the Oregon law is a prosecutable crime carrying serious penalties under the provisions of the Federal CSA.

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[2] Title 21, United States Code, Sections 801 *et seq.*

Under the CSA it is a federal crime for a physician to "dispense" a controlled substance without a legitimate medical purpose in the usual course of medical treatment.[3] See Title 21, United States Code, sections 841(a)(1), 802 (21); 829; 21 CFR § 306.04(a) (1973) (re-designated as 21 CFR § 1306.04(a) (1975); see also *United States v. Moore,* 423 U.S. 122, 124, 139 (1975) (holding that physician can be convicted under the CSA when acting outside professional limits). When "death ... results from the use of such substance" dispensed, the dispensing physician faces significant penalties under the CSA. See, 21 U.S.C. § 841 (b)(1)(C) (prescribing up to life in prison for dispensing Schedule II controlled substances in violation of §841(a) where death results from the use of the drug) see also *Moore*, 423 U.S. at 132 (1975) (recognizing that Congress geared the CSA's penalties "to the nature of the violation, including the character of the drug involved.").

It is worth noting that Congress also expressed disapproval of physician-assisted suicide in its Assisted Suicide Funding Restriction Act of 1997, Pub. L. 105-12,

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[3] Whether the physician acted outside authorized professional limits is not an element of the offense that the government needs to negate; rather, it is an affirmative defense available to the practitioner who carries the burden of going forward with the evidence concerning the exception. 21 U.S.C. § 885(a)(1); *United States v. Steele*, 147 F.3d 1316, 1318-1320 (11th Cir. 1998)(en banc) (and cases cited therein), cert. denied, *Steele v. United States*, 528 U.S. 933 (1999). Congress clearly did not intend an exception for non-medical use of controlled substances for purposes harmful to life. There is no expression within the CSA of any such exception. Permitting states to alter the CSA by injecting such an exception holds the potential to gut it. Under the appellate court's decision, for example, California could pass a law permitting physicians to prescribe and dispense controlled substances to assist patients to get "high" in order to deal with stress.

Apr. 30, 1997, 111 Stat. 23, *codified at* 42 U.S.C. § 14401 et seq., Congress's stated principal purpose of the Act was "to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual." 42 U.S.C. § 14401(b).

Article VI of the United States Constitution states:

> This Constitution, and *the Laws of the United States* which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the . . . laws of any State to the Contrary notwithstanding. U.S. Const. art. VI (emphasis added)

The Federal CSA expressly preempts state laws to the extent "there is a positive conflict between [a provision of the CSA] and that state law so that the two cannot consistently stand together." 21 U.S.C. 903. To be sure, nothing in the CSA prevents a state from enacting its own stricter drug legislation, or prosecuting drug offenses at the state level. *Id.* And, nothing in the Federal CSA preempts a state from regulating within the field of physician assisted suicide, (i.e., nothing in the CSA preempts a state law authorizing physician assisted suicide *per se*). Under conventional conflict preemption principles, however, the Federal CSA clearly preempts Oregon's statute authorizing *the dispensing of controlled substances* to assist suicide. The CSA proscribes the dispensing of controlled substances by physicians without a legitimate medical purpose in the usual course of medical treatment -- and provides severe penalties when "death ... results from the use of such substance...." See, §§841(a)(1), 802 (21), 829; 21 CFR § 1306.04(a)

(1975); *Moore,* 423 U.S. at 124 (1975); and 21 U.S.C. 841 (b)(1)(C). Oregon's law, on the other hand, expressly authorizes - and immunizes against prosecution - the lethal dispensing proscribed and severely penalized in the CSA. Thus, the two statutes here conflict to the extent they cannot consistently stand together.

Moreover, even if the CSA did not expressly preempt the Oregon statute, implied preemption exists where "compliance with both federal and state regulations is a physical impossibility." *Boggs v. Boggs*, 520 U.S.833, 844 (1997) (internal quotation marks omitted), citing *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 98 (1992). The mutually exclusive provisions of the CSA and Oregon law governing the dispensing of controlled substances make it impossible for a dispensing physician to comply with both. In such situations this Court has deemed the state law preempted – even where a distinctive state interest is at stake. See e.g., *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 581 (1979) (finding state community property law preempted by federal military pay law).

Thus, the Ninth Circuit's analysis, granting Oregon's request to enjoin the United States from enforcing the Federal CSA, is incompatible with the Supremacy Clause in Article VI of the United States Constitution. The CSA and its implementing regulations plainly proscribe, and therefore preempt, Oregon's law authorizing the dispensing of drugs to assist in the death of a human being -- even *without considering* the Attorney General's statutorily authorized reasonable interpretation of the CSA's implementing regulation at issue here. As discussed in more detail in the next section, this interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 136.04. Pet. App.

100a (AG Order no. 2534-2001). When this reasonable interpretation of the CSA's implementing regulation is added into the analysis, the certainty of federal preemption is irrefutable. [4]

B. The Attorney General Acted within His Statutory Authority

The court of appeals erred when it held that the interpretive rule promulgated by the Attorney General fell outside his statutory authority. Pet. App. 9a (court of appeals opinion).

As previously discussed, the Attorney General's interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA. It also verified that helping one to kill oneself is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 136.04. Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg at 56,608). The interpretive rule further concluded that "[s]uch conduct

[4] The Ninth Circuit's analysis incorrectly presumes this case is about Oregon's right to regulate the practice of medicine -- suggesting that the Attorney General's ruling alters the usual constitutional balance between the states and federal government. Pet. App. at 11a (court of appeals opinion). First, the appellate court over-states Oregon's situation, given that Oregon stands alone among the fifty states in having radically departed from accepted medical practice. Physician-assisted suicide bills in more than 20 states have failed in the past decade, whereas 16 bills prohibiting it have in the past decade and a half been enacted. Yale Kamisar, *The Rise and Fall of the "Right" to Assisted Suicide*, in Foley & Hendin, eds., *The Case Against Assisted Suicide, For the Right to End-of-Life Care 91* (2002) (citations omitted). Second, and more importantly, the court's federalism analysis analyzes oranges when this case is about apples. This case is not about the regulation of medical practice, but about the right of the federal government to regulate controlled substances in a uniform manner.

by a physician registered to dispense controlled substances *may* 'render his registration ... inconsistent with the public interest' and therefore subject to *possible* suspension or revocation." *Id.* quoting 21 U.S.C. § 824(a)(4)(emphasis added). For the reasons discussed below, the Attorney General acted within statutory authority when he promulgated this interpretive rule.

Congress, through the CSA, used the concept of "registration" to identify those physicians who operate "beyond the bounds of professional practice." *Moore*, 423 U.S. at 139 (1975). Physicians and others, who dispense a controlled substance, must "obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him." 21 U.S.C. § 822 (a)(2). Under the CSA, physicians and others registered by the Attorney General to dispense controlled substances are authorized to dispense such substances only "to the extent authorized by their registration and in conformity with the [provisions of the CSA]." 21 U.S.C. § 822 (b). Thus, only "the lawful acts of registrants are exempted" from prosecution. *Moore*, 423 U.S. at 130 (1975).

Congress expressly granted the Attorney General the authority "to promulgate rules and regulations ... relating to the registration and control of the...dispensing of controlled substances and to the registration and control of regulated persons and regulated transactions" 21 U.S.C. § 821.[5]

Under 21 U.S.C. § 823 (f), Congress gave the Attorney General the express authority to deny an

[5] Congress expressly further granted the Attorney General the authority to "promulgate and enforce any rules, regulations, and procedures" deemed "necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b).

application for registration "if he determines the issuance of such registration is inconsistent with the public interest." Moreover, Congress also expressly gave the Attorney General the authority to suspend or revoke a registration authorized pursuant to section 823 if the Attorney General finds that the registrant committed an act that would "render his registration under section 823 [of the CSA] inconsistent with the public interest as determined under such section." 21 U.S.C. § 824.

In denying, revoking or suspending an application, the Attorney General must consider the following factors in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience dispensing ... controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823

Most of the drugs dispensed in the lethal conduct authorized by the Oregon law likely fall within Schedule II of the CSA, the "most strictly regulated category of substances available for non-research purposes." Pet. App. 114a (Memorandum for the Attorney General, June 27, 2001). *See also* Pet. App. 65a (opinion of the district court).

In 21 U.S.C. 829, Congress mandated the following in connection with the dispensing of Schedule II controlled substances:

> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II...may be dispensed without the written prescription of a practitioner, [with emergency exceptions not relevant to the discussion at bar]."[6]

Pursuant to the above discussed rulemaking authority vested in the Attorney General by Congress, the Attorney General, in the early 1970's, enacted regulations pursuant to Section 829:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice... An order

[6] The word "dispense" means "to deliver a controlled substance to an ultimate user... by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance...." Title 21, United States Code, Section 802 (10). "'Ultimate user' means a person who has lawfully obtained ... a controlled substance for his own use...." 21 U.S.C. § 802 (27). The term "practitioner" includes a "physician ... licensed, *registered*, or otherwise permitted, by the United States or the jurisdiction in which he practices ... [to] dispense ... a controlled substance in the course of professional practice...." 21 U.S.C. § 802 (21) (emphasis added).

> purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning of this Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provide for violations of the provisions of law relating to controlled substances.

21 CFR § 306.04(a) (1973) (redesignated as 21 CFR § 1306.04(a) (1975)[7]

If the Attorney General in the early 1970's promulgated the above rule pursuant to statutory authority, then the Attorney General in 2001certainly had the authority to interpret what it means. Indeed, as noted above, Congress, in 21 U.S.C. § 821, expressly granted the Attorney General authority "to promulgate rules and regulations ... relating to the registrations and control of the...dispensing of controlled substances and to the registration and control of regulated persons and regulated transactions." The Attorney General's interpretive ruling directly promotes the CSA's purposes, by restricting use of controlled substances to legitimate medical purposes. It promotes the medical use of drugs, furthering the public interest in a manner perfectly consistent with the broad intent of Congress. Thus, when the Attorney General published the interpretive rule confirming that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 136.04, he acted

[7] See also, 21 U.S.C. 830 (b)(3)(ii) *Regulation of listed Chemicals – Mail order reporting* – "The term 'valid prescription' means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to ...prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice."

well within his Congressional authorized authority. Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg. at 56,608).

Moreover, it was reasonable for the Attorney General to subsequently conclude in the interpretive rule that "[s]uch conduct by a physician registered to dispense controlled substances *may* 'render his registration ... inconsistent with the public interest' and therefore subject to *possible* suspension or revocation." Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg at 56,608 quoting 21 U.S.C. § 824(a)(4)) (emphasis added).

The court of appeal's holding that the Attorney General's action exceeded statutory authority because it "evaluates public interest under 21 U.S.C. § 823 without considering all five factors required by that subsection" is misplaced. Pet. App. 17a (court of appeals opinion).

This part of the Attorney General's interpretive rule is merely public notice of a logical consequence that *may* come to one from ignoring the previously established premise that dispensing drugs to assist one to kill oneself is not a legitimate medical practice and violates the CSA. In this regard, although the Attorney General certainly evaluated the public's interest in promulgating the interpretive rule, nothing in the law requires him to consider all five factors delineated in 21 U.S.C. §823(f). Under the CSA, the Attorney General is required to consider these five factors only when denying, revoking or suspending an application for a registration. 21 U.S.C. §§ 823 (f), 824. Nothing in the record indicates that the Attorney General has even contemplated taking such action against the named plaintiffs. Thus, the court of appeals erred since no statutory authority required the Attorney General to consider the five factors when promulgating the interpretive rule.

C. Enjoining the United States from Protecting the Citizenry against Dispensing Drugs to Kill a Human Being, Creates a Culture of Death with Grave Implications

The court of appeals mandated that the United States must not enforce the nation's drug laws against physicians who dispense controlled substances to assist in the killing of a human being. *Amici* believe that human beings are made in the image of God and that therefore every life is sacred. *Genesis* 1:26 (NIV) Underlying the court of appeals decision is a rejection of this inviolable standard present in the natural law, divine law, and positive law, in favor of a morally relative standard where each individual chooses when and whether a human life has positive value.

Ultimately, allowing the dispensing of federally controlled drugs for assisting suicide proceeds from the fundamentally erroneous premise that human life in certain conditions has no positive value. That premise has incalculably grave implications for all of us. Here an appellate court ruled that individuals have the right to take life in one situation, and that the United States cannot enforce the federal drug laws in ways that protect life. When we abandon moral absolutes today, it becomes easy tomorrow to choose death in other ways, for other people, in other situations, since the positive value of life has become an immorally relative individual choice.

The prominent ethicist Sissela Bok concluded, "No society has yet worked out the hardest questions of how to help those patients who desire to die, without endangering others who do not." Sissella Bok, *Physician-Assisted Suicide*, in Euthanasia and Physician-Assisted Suicide 139 (Gerald Dworkin, et al., eds., (1998).

Prior to the enactment of the Federal CSA,[8] euthanasia societies grew during the late 19th and early 20th century eugenics movements in the United States and Europe. Kathleen Foley, and Herbert Hendin, *Introduction*, in The Case Against Assisted Suicide, For the Right to End-of-Life Care 6-7 (Foley & Hendin, eds 2002). Thirty states passed sterilization laws embraced by Presidents Theodore Roosevelt and Woodrow Wilson. *Id.*

The Nazis legalized voluntary euthanasia, then involuntarily euthanized hundreds of thousands of the mentally ill, then extended euthanasia's reach to Jews, gypsies, and other "undesirables." *Id.* at 7.

As late as the 1940s this country's leading euthanasia proponent Dr. Foster Kennedy continued to advocate compulsory euthanasia for retarded children on eugenics grounds. By the 1970s the euthanasia movement's focus shifted to easing the "burden" of caring for the elderly, and then to easing suffering, *id.* at 8 – though notably, no suffering requirement exists in the Oregon law which purports instead to be based on personal choice. The Oregon law requires the physician to advise the patient of palliative care and hospice but does not require that the physician have any training in either and requires no palliative care consultation. The law's data collection requirements are so meager – the form used requires no disclosure of the reason for the patient's request – that study of the Oregon experiment is limited. *Id.* Oregon's law grants "good faith" immunity to the physician and has no enforcement

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[8] The Ninth Circuit erred in relying on the former Attorney General Reno's January 5, 1998 letter suggesting that the CSA did not prohibit prescription-assisted suicide. *See* Pet. App. 7a. The Reno letter assumed, ahistorically, that the CSA was written before there was any consideration of assisted suicide.

mechanism for physician non-compliance, while failing utterly to protect the family.

The Dutch experiment in physician assisted suicide failed frighteningly. The three foreign clinicians who were permitted close study, including case discussion and extensive interviews, independently determined that the Dutch legal requirements were consistently violated and could not be enforced. Foley, et al., *supra*, at 10. Sixty percent of Dutch assisted suicide cases go unreported. *Id.* Most non-reporting involves cases in which physicians have failed to follow established guidelines for voluntariness or consultation.

Worse, in several thousand cases, each year physicians ended their patient's life without the patient's consent. *Id.*at10. Twenty-five percent of physicians terminated one or more patient's life without request. *Id.* In the 1995 study year, 40 percent of the more than 6,000 cases in which physicians actively intervened to cause death involved no explicit request from the patient. Herbert Hendin, *The Dutch Experience*, in Foley, ed., *supra*, at 105; *see also* Zbigniew Zylicz, M.D., *Palliative Care and Euthanasia in the Netherlands: Observations of a Dutch Physician*, in Foley, ed., *supra*, at 123.

Each major Dutch measure to control physician-assisted suicide, including informed consent, consultation, and reporting, largely failed, was modified, or was violated. Hendin, *supra*, at 103, *citing* C. Gomez, *Regulating Death: Euthanasia and the Case of the Netherlands* (1991). This Court in *Washington v. Glucksberg*, 521 U.S. 702, 733 (1997), recognized "that what is couched as a limited right to 'physician-assisted suicide' is likely, in effect, a much broader license, which could prove extremely difficult to

solve and contain." Indeed, what we sow today, we will reap tomorrow.

As the fundamental units of society, families must be protected and promoted by the law and by legal institutions, if order and liberty are to flourish. Yet clinical research shows that suicides in general and physician-assisted suicides more particularly, devastate families. M.D. Reed and J.Y. Greenwald, *Survivor Victim Status, Attachment and Sudden Death Bereavement*, 21 J. of Suicide and Life-Threatening Behavior 385-401 (1991); N.L. Farberow, D.E. Gallagher-Thompson, N.J. Gilewski, and L.W. Thompson, *Changes in Grief and Mental Health of Bereaved Spouses of Older Suicides*, 47 J. Gerontology 357-66 (1992), both cited in Kathleen Foley, and Herbert Hendin, *The Oregon Experiment*, in The Case Against Assisted Suicide, For the Right to End-of-Life Care 158 (Foley, ed. 2002) ("devastating grief and guilt that we see in survivors of suicide"). Imagine the shock of an adult child making the weekly visit to a parent's nursing home, only to discover that a physician proscribed and dispensed a federally controlled substance to help the parent commit suicide the day before. (Oregon's law requires no pre-suicide notification to families.)

The toll on family life is incalculable. Allowing physicians to dispense drugs to assist in killing has an insidious effect on families who support seniors, burdening both the family and the dying. The number of patients in Oregon reporting a concern about being a burden on the family increased from 12 percent in 1998 to 63 percent in 2000, subsequent to the passage of Oregon's physician-assisted suicide law. *Id.* at 162. Physician-assisted suicide creates in practice a frightening "duty to die" – frightening because the practice of physician-assisted suicide has been shown to be so imperfect a means of death that in one Dutch

study fully 20 percent of patients given what was considered to be a lethal dose lived for more than three hours, in some cases requiring the physician to intervene with a lethal injection which would be illegal under the Oregon law. *Id.* at 166, *citing* J.H. Groenewould, A. van der Heide, B.D. Onwuteaka-Philipsen, D.L. Willems, P.J. van der Maas, and G. van der Wal, *Clinical Problems with the Performance of Euthanasia and Physician-Assisted Suicide in the Netherlands*, 342 New England J. Med. 551-56 (2000). Families are occasionally called on to intervene with pillows or plastic bags. Foley & Hendin, *supra* at 164, *(citations omitted).*

The Hippocratic Oath written during the fifth to fourth centuries B.C. declares, "I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect." The AMA and more than 40 other national and state medical and health care organizations have urged on this Court that "the ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics"; that the AMA has "reexamined and reaffirmed" the prohibition against physician-assisted suicide; and that "physician-assisted suicide remains 'fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks.'" Brief of the American Medical Assn., American Nurses Assn., American Psychiatric Assn., et al., as Amicus Curiae in Support of Petitioners at 5, *Glucksberg* (No. 96-110), available in 1996 WL 656263.

The court of appeals decision rejects this position and the underlying inviolable standard which serves as its foundation. Underlying its decision instead is a morally relative foundation, where each individual chooses when and whether a human life has positive value. The grave implications for our nation that accompany such a choice are

clear. Foundations do matter. Today this Court stands at the statutory construction site and *amici* urge it to grant the government's petition for certiorari.

CONCLUSION

This case implicates important federalism concerns vital to proper constitutional governance under the rule of law. Mutually exclusive provisions of the Federal CSA and Oregon law make it impossible for a dispensing physician to comply with both laws. Thus, the Federal CSA preempts the Oregon law. The appellate court's analysis granting Oregon's request to enjoin the United States, from enforcing the Federal CSA, is therefore incompatible with the Supremacy Clause in Article VI of the United States Constitution.

The Attorney General's interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose." The Attorney General, in promulgating this rule, acted well within a plethora of statutory authority expressly allowing him to do so.

Amici ask that this Court restore the right of the federal government to enforce our nation's drug laws under the CSA. Undeniably, we stand at a statutory construction site. If, in the name of an individual's morally relative choice, we enjoin the federal government from proscribing the dispensing of drugs to kill a human being, we merely create an illusion of a nation willing to protect fundamental freedoms. Such a course inevitably erodes the fundamental foundations of our country, as structural institutions of free government stand for a time, while the essence for which they stand cease to exist. Who we are morally as a nation is

a fabric made up of much more than statutes and court decisions. Those who came before us built a constitutional democratic republic upon fundamental foundations of decency. It is now our watch. It is well for us to recall, therefore, the ancient truth that "righteousness exalts a nation." *Proverbs* 14:34 (NIV).

A*mici* urge this Court to grant the Petition for Certiorari.

Respectfully submitted,

WILLIAM WAGNER
NELSON P. MILLER
Counsel of Record

STEPHEN W. REED
35 N. Lake Ave.
Pasadena, CA 91101
(626) 449-4521

PATRICK A. TRUEMAN
801 G. Street NW
Washington D.C. 20001
(202) 393-2100

COOLEY LAW SCHOOL
300 South Capitol
Lansing, MI 48933
(517) 371-5140

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In the Supreme Court of the United States

JOHN ASHCROFT, Attorney General, et al.,

Petitioners,

v.

STATE OF OREGON, et al.,

Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR RESPONDENT STATE OF OREGON IN OPPOSITION

HARDY MYERS
Attorney General of Oregon
PETER SHEPHERD
Deputy Attorney General
***MARY H. WILLIAMS**
Solicitor General
ROBERT M. ATKINSON
Assistant Attorney General
400 Justice Building
Salem, Oregon 97301-4096
Phone: (503) 378-4402
Counsel for Respondents

*Counsel of Record

QUESTION PRESENTED

Exercising its traditional police powers, Oregon enacted laws and regulations that allow physicians to prescribe and pharmacists to dispense Schedule II controlled substances to competent, terminally-ill adults who may use them under strictly regulated conditions to choose the time, place, and manner of their impending deaths. In enacting and amending the Controlled Substances Act (CSA), did Congress clearly authorize the Attorney General to determine that physicians and pharmacists acting in accordance with those Oregon laws have violated the CSA?

TABLE OF CONTENTS

Page

Question Presented i

Opinions Below 1

Jurisdiction 1

Statement 1

Argument 9

Conclusion 19

Supplemental Appendix

TABLE OF AUTHORITIES

Page

Cases Cited

Gregory v. Ashcroft,
501 U.S. 452 (1990) 11

Hill v. Colorado,
530 U.S. 703 (2000) 15

Lee v. State of Oregon,
107 F.3d 1383 (9th Cir. 1997),
cert. den. 522 U.S. 927 (1997) 9

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996) 15, 18

Norfolk S. Railway Co. v. Shanklin,
529 U.S. 344 (2000) 8

Raich v. Ashcroft,
352 F.3d 122 (9th Cir. 2003),
cert. granted 124 S. Ct. 2909 (2004)..... 16

Raygor v. Regents of the University of Minnesota,
534 U.S. 533 (2002) 11

Reid v. Colorado,
187 U.S. 137 (1902) 11

Solid Waste Agency of Northern Cook Cty. v. Army Corps of Engineers,
531 U.S. 159 (2001) 8, 12, 13, 17

United States v. Moore,
423 U.S. 122 (1975) 7, 13, 16

United States v. Moore,
505 F.2d 426 (D.C. Cir. 1974)..... 17

United States v. Oakland Cannabis Buyers' Cooperative,
532 U.S. 483 (2001) 16

Washington v. Glucksberg,
521 U.S. 702 (1997) 4, 6, 7, 10, 15

Will v. Michigan Dept. of State Police,
491 U.S. 58 (1989) 11, 15

Constitutional and Statutory Provisions

21 U.S.C. § 801 16

21 U.S.C. § 802(21) 5

21 U.S.C. § 811(f) 16

21 U.S.C. § 821(f) (1970) 14

21 U.S.C. § 823(f) 14

21 U.S.C. § 903 17

21 U.S.C. § 811(f) 3

28 U.S.C. § 1254(1) 1

Or. Rev. Stat. § 127.800(7) 2

Or. Rev. Stat. § 127.800(8) 2

Or. Rev. Stat. § 127.805 1

Or. Rev. Stat. § 127.815 2

Or. Rev. Stat. §§ 127.800 through 127.995 1

Or. Rev. Stat. § 127.800(12) 1

U.S. Const. Art. VI, § 2 11

Administrative Rules

21 C.F.R. § 1306.04 5

21 C.F.R. § 1306.04(a) (1971) 14

Other Authorities

Dispensing of Controlled Substances to Assist Suicide,
66 Fed. Reg. 56,607 (2001) 5

H.R. 4006, 105th Cong. (1998) 18

H.R. 2260, 106th Cong. (1999) 18

S. Rep. No. 98-225, 98th Cong., 2d Sess. (1984) 14

Wesley G. Harline, M.D.,
Continuation of Registration with Restrictions,
65 Fed. Reg. 5665 (2000) 4

William F. Skinner, M.D.,
Continuation of Registration,
60 Fed. Reg. 62,887 (1995) 4

OPINIONS BELOW

The opinion of the Court of Appeals, Pet. App. 1a-63a, is reported at 368 F.3d 1118. The opinion of the District Court, Pet. App. 64a-97a, is reported at 192 F. Supp. 2d 1077.

JURISDICTION

The judgment of the Court of Appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004. Pet. App. 98a-99a. The petition for a writ of certiorari was filed on November 9, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATEMENT

In 1994, the people of Oregon enacted by initiative the Death With Dignity Act (DWDA). Or. Rev. Stat. §§ 127.800 through 127.995. The DWDA establishes tightly controlled procedures under which competent, terminally-ill adults who are under the care of an attending physician may obtain a prescription for Schedule II controlled substances in sufficient kind and quantity to allow them to control the time, place, and manner of their own impending death. Or. Rev. Stat. § 127.805; Pet. App. 163a.[1] The attending physician must determine, among other things, the patient's mental competence, Oregon residence, and diagnosis and prognosis. Or. Rev. Stat. §

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[1] To qualify as "terminally ill" a person must have "an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months." Or. Rev. Stat. § 127.800(12).

127.815; Pet. App. 163a-165a. The attending physician must inform persons requesting those substances of their diagnosis and prognosis, the risks and probable results of taking the medication, and alternatives to taking their own lives, including, but not limited to, hospice care and pain relief. Or. Rev. Stat. § 127.800(7); Pet. App. 162a. A consulting physician must confirm the attending physician's medical opinion. Or. Rev. Stat. § 127.800(8); Pet. App. 162a. Once a request from a qualifying patient has been properly documented and witnessed, and all waiting periods have expired, the attending physician may prescribe, but not administer, medication to enable the patient to end his or her life in a humane and dignified manner.[2] The DWDA immunizes physicians and pharmacists who act in compliance with its comprehensive procedures from civil or criminal sanctions, or professional disciplinary actions based on that conduct. The

[2] The DWDA is sometimes referred to as authorizing "physician-assisted suicide." That description is potentially misleading. As described in the text, the DWDA authorizes physicians to prescribe and pharmacists to dispense controlled substances that will permit a patient to choose a painless death, but it does not authorize either to administer those substances to the patient. Moreover, as also described in the text, only a very limited category of persons qualify in a very limited number and type of circumstances to receive those substances. It is only within the carefully circumscribed boundaries established by those limitations that the phrase "physician-assisted suicide" can be considered accurate as applied to the DWDA.

DWDA also requires healthcare providers to file reports with the State documenting their actions.[3]

When some members of Congress complained to then-Attorney General Janet Reno that the DWDA authorized a use of controlled substances that violated the Controlled Substances Act (CSA), she disagreed. After a "thorough and careful review" by the Justice Department, Attorney General Reno concluded that the CSA was intended "to prevent both the trafficking in [controlled] substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress sought to prevent was that deriving from the drug's 'stimulant, depressive, or hallucinogenic effect on the central nervous system.' 21 U.S.C. § 811(f)." Supp. App. 3-4. Attorney General Reno could find no evidence that, "in the CSA, Congress intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." *Id.* at 4. The Attorney General noted that the CSA was "essentially silent" about "regulating the practice of medicine that involves legally available drugs," with one exception dealing with treating addicts. "Even more fundamentally, there is no evidence that

[3] Since November 1997, when the people of Oregon approved the DWDA for the second time, a total of 171 patients have self-administered Schedule II controlled substances prescribed under the Act. *See* Sixth Annual Report on Oregon's Death with Dignity Act, Table 1 p. 19 (March 10, 2004), http://www.dhs.state.or.us/publichealth/chs/pas/ar-index.cfm (as visited December 14, 2004).

Congress, in the CSA, intended to assign the [Drug Enforcement Agency] the novel role of resolving the 'earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide,' *Washington v. Glucksberg*, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances." *Ibid.* Determining whether conduct permitted by the DWDA "falls outside the legitimate practice of medicine and is inconsistent with the public interest," "are fundamental questions of morality and public policy" that are "well beyond the purposes of the CSA." *Ibid.*[4]

But as the Court of Appeals noted, "[w]ith a change of administrations came a change of perspectives." Pet. App. at 8a. Relying primarily on a regulation providing that a prescription for a controlled substance is "effective" only if issued for a "legitimate medical purpose,"

[4] Attorney General Reno's view that Congress delegated only limited authority to the Attorney General to address medical practices was applied for years by the DEA in administering the CSA. *See, e.g.*, Wesley G. Harline, M.D., Continuation of Registration with Restrictions, 65 Fed. Reg. 5665 (2000) (declining to revoke physician's CSA registration where there were differences of opinion in the medical community over whether a particular use of controlled substances served any legitimate medical purpose because "it is not DEA's role to resolve these differences and set the standard for the medical community"); William F. Skinner, M.D., Continuation of Registration, 60 Fed. Reg. 62,887 (1995) (DEA will not attempt to decide whether a particular practice serves a legitimate medical purpose if "the medical community has not reached a consensus" on the issue).

21 C.F.R. § 1306.04, Attorney General John Ashcroft issued a directive (Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607; Pet. App 100a through 105a), concluding that physicians who prescribe controlled substances in compliance with the DWDA violate the CSA, making them subject to sanctions including criminal prosecution and loss of their ability to prescribe controlled substances.[5]

Seeking to protect not only its physicians, but also its sovereign ability to implement the will of Oregon's people by providing competent, terminally-ill adults with a right Oregonians twice voted to confer, Oregon brought suit in the United States District Court for the District of Oregon. The State asserted, in part, that the Ashcroft Directive exceeded the Attorney General's authority because Congress did not intend to authorize the Attorney General to override a State's regulation of the practice of medicine.[6] A doctor, a pharmacist, and several terminally-ill Oregonians intervened.

[5] The CSA applies to "practitioners," which, in general terms, it defines to include physicians, dentists, veterinarians, scientific investigators, pharmacists, and others who are licensed by the United States or the jurisdiction in which they practice to distribute, dispense, or conduct research on or analysis of controlled substances. 21 U.S.C. § 802(21); Pet. App. 149a. For convenience, and because Oregon's law applies only to physicians and pharmacists, this brief generally refers to physicians.

[6] Oregon also asserted that if Congress had intended to displace the State's authority in this particular context, it would have exceeded its power under the Commerce Clause.

The District Court agreed that nothing in the CSA supports the Attorney General's conclusion that Congress intended to substitute his judgment for the historic authority of the State to determine the scope of legitimate medical practice. Consequently, the court permanently enjoined enforcement of the Ashcroft Directive. The District Court began with this Court's opinion in *Washington v. Glucksberg*, 521 U.S. 702 (1997), which, the court noted, acknowledged the "earnest and profound debate" about end-of-life treatment occurring in the States. Pet. App. 66a-67a. Although the District Court agreed that the CSA gives the Attorney General and Drug Enforcement Agency (DEA) "broad authority to regulate controlled substances," the court concluded: "No provision of the CSA, however, alone (as defendants urge) or viewed as a 'symmetrical and coherent scheme' demonstrates or even suggests that Congress intended to delegate to the Attorney General or the DEA the authority to decide, as a matter of national policy, a question of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice." Pet. App. 87a. Nor could the court find support for the Attorney General's position in the legislative history of the CSA. Rather, that history overwhelmingly supported the conclusion "that Congress' intent was to address problems of drug abuse, drug trafficking, and diversion of drugs from legitimate channels to illegitimate channels." *Id.* at 89a-90a. Finally, the court noted that none of the cases on which the Attorney General relied involved doctors or

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Neither the District Court nor the Court of Appeals found it necessary to reach that question.

pharmacists who were acting in compliance with state law. *Id.* at 92a-93a, *citing*, *inter alia*, *United States v. Moore*, 423 U.S. 122 (1975). In concluding, the court stated: "The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. * * * The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board." Pet. App. 94a-95a.

The Attorney General appealed, and the Court of Appeals affirmed. That court, too, began its analysis with *Glucksberg*. Pet. App. 9a. The court noted this Court's statement that determining whether to permit physicians to aid those who wished to hasten death "belongs among state lawmakers," *ibid.* (citing *Glucksberg*, 521 U.S. at 735) in the "'laboratory' of the States." *Ibid.* (quoting 521 U.S. at 737 (O'Connor, J., concurring)). As the District Court had, the Court of Appeals explained that States bear and historically have borne primary responsibility for regulating medical care. Pet. App. 10a. Therefore, unless the federal statute in question is "unmistakably clear," the courts will not conclude that Congress intended to alter that federal balance. *Id.* at 11a. And, as the District Court did, the appeals court concluded that "Congress has provided no indication—much less an 'unmistakably clear' indication—that it intended to authorize the Attorney General to regulate" in this context. *Id.* at 12a. The Court of Appeals' review of the legislative history confirmed that Congress was concerned with drug abuse, drug addiction, and the diversion of controlled substances out of legitimate channels, not with substituting the Attorney General for state regulators. *Id.*

at 18a-20a. Because Congress had not expressed its clear intention to replace the States as the regulators of medical practice, the court concluded that it was "under no obligation to defer to the Attorney General's interpretation of his role under the statute and its implementing regulations." *Id.* at 21a. And the court noted that this Court refused to extend deference to an agency's interpretation of a regulation "where, as here, it conflicts with the agency's previous interpretation of the same regulation." *Id.* at 23a, n. 11, *citing Norfolk S. Railway Co. v. Shanklin*, 529 U.S. 344, 356 (2000), and *Solid Waste Agency of Northern Cook Cty. v. Army Corps of Engineers*, 531 U.S. 159, 168 (2001).

The dissenting opinion concluded that the Attorney General's interpretation of the "legitimate medical purpose" regulation was valid and controlling. Generally rejecting the majority's analysis, the dissent determined that the CSA was not limited to combating drug abuse, Pet. App. 34a-36a; that Congress did not intend to preserve the States' traditional authority over the practice of medicine if that practice involved controlled substances, *id.* at 36a; and that the "clear statement" rule does not apply to the CSA. *Id.* at 45a-47a. Ultimately, the dissent concluded that the Ashcroft Directive was an interpretation of the agency's "legitimate medical purpose" regulation, not an interpretation of the CSA itself, *id.* at 54a, and it was therefore entitled to be judged under a "highly deferential standard of review." *Id.* at 55a. Applying that standard, the dissent had no difficulty in finding the Ashcroft Directive to be conclusive. *Id.* at 56a.

ARGUMENT

Because the DWDA is unique to Oregon, petitioner is understandably unable to claim that the Court of Appeals' decision in this case conflicts with decisions of other circuits. Consequently, he is left to assert that this Court should grant review because the Court of Appeals' opinion is inconsistent with this Court's cases and therefore wrong, that the opinion threatens federal supremacy, and that this case has national significance because it involves a ground-breaking policy choice with which many disagree. But neither the permissibility nor the wisdom of Oregon's policy choice is at issue here.[7] What is at issue—whether Congress authorized the Attorney General to overrule a State's decision about specific medical uses of controlled substances that admittedly have approved medical uses—is a narrow question of statutory construction calling for the application of settled principles. And notwithstanding petitioner's assertions, the Court of Appeals correctly applied this Court's precedents. Review by this Court is therefore not warranted.

1. The Attorney General places the policy choice embodied in the DWDA at the forefront of his argument. Pet. Cert. 11-13. He describes Oregon's decision to permit physicians to assist mentally-competent, terminally-

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[7] Oregon successfully defended a direct challenge to the substance of the DWDA shortly after that law's enactment, *Lee v. State of Oregon*, 107 F.3d 1383 (9th Cir. 1997), *cert. den.* 522 U.S. 927 (1997), and petitioner does not suggest that the DWDA is invalid. He asserts only that his authority over controlled substances allows him to prevent their use for purposes authorized by the Oregon law.

ill adults in choosing the time, place, and manner of their own impending deaths as a radical departure from long-accepted legal and ethical norms that is at odds with the decisions of the remaining states, the opinions of certain medical associations, and tradition. *Ibid.* Oregon does not, nor could it, deny that its choice is controversial; this Court has already acknowledged the serious, complex, and unsettled nature of the question presented by end-of-life decisions, particularly in the light of modern medical means of prolonging life. *Glucksberg*. But even if Oregon conceded that it stood alone in its views about end-of-life care,[8] whether a State can authorize physicians to assist those who seek to avoid intolerable pain and loss of control and dignity at the end of their lives is not at issue here. At most, this case is about the means those physicians may use. Consequently, the only questions this case presents are whether, in enacting the CSA, Congress intended to supercede the States' historic police powers over the practice of medicine, and, even if it did, whether it intended to authorize the Attorney General to decide the specific uses state-licensed physicians may make of controlled substances that admittedly have approved medical uses.

2. Suggesting that this case involves a broad attack on a generally accepted principle, *see Glucksberg*, 521 U.S. at 770 (Souter, J., concurring in the judgment), the petition expansively asserts that the Court of Appeals' decision

[8] It does not. As this Court recognized in *Glucksberg*, the subject addressed by the DWDA is an issue of earnest, widespread, and ongoing debate among citizens, lawmakers, ethicists, and medical professionals throughout the nation.

threatens to give States supremacy over federal law and turn the "proper relationship between the federal and state governments under the Constitution on its head." Pet. Cert. 9. That, too, overstates the issue. This Court has explained that, under our federal system, the promise of liberty lies in "the tension between federal and state power." *Gregory v. Ashcroft*, 501 U.S. 452, 459 (1990). That tension necessarily creates questions about "who gets to decide." *See* Pet. App. 9a. The Supremacy Clause, U.S. Const., Art. VI, § 2, even if not the ultimate weapon, certainly gives Congress an obvious advantage in most contests about decision-making authority within the federal system. *See Gregory*, 501 U.S. at 460. Nevertheless, the States "retain substantial powers under our federal scheme, powers with which Congress does not readily interfere." *Raygor v. Regents of the University of Minnesota,* 534 U.S. 533, 544 (2002).

When Congress legislates in those traditionally state-controlled areas, it "alter[s] the usual constitutional balance between the States and the Federal government." *Id.* at 543 (internal quotation marks omitted). Even where there is no doubt that Congress *can* do that, "it must make its intention to do so unmistakably clear in the language of the statute." *Ibid., quoting Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989). Resolving those who-gets-to-decide questions is hardly a new project for this Court; and while the tide of federal power has ebbed and flowed over the years, some principles, including the "clear statement" requirement, have remained firm for many years. *See, e.g., Reid v. Colorado*, 187 U.S. 137, 148 (1902) (even when Congress may supercede the police powers of the States, Court will never

hold that it has done so unless "its purpose to effect that result is clearly manifested").

Thus, the issue actually presented here reduces to a straightforward question of statutory construction governed by the long-established "clear statement" rule: Does the CSA clearly empower the Attorney General to overrule a state law determination about specific medical uses of controlled substances that concededly have approved medical uses under the CSA?

In asserting that the CSA does precisely that, the Attorney General focuses his attention on controlled substances. He insists that Congress has given him plenary authority over all permissible uses of those substances: that he can reschedule them virtually at will, Pet. Cert. 14, 16; and that he can tell doctors what substances they can prescribe for what medical purposes by decreeing that any specific use of which he disapproves is not a "legitimate medical purpose." *Id.* at 17.[9] Consequently, he asserts, the courts must defer to the Ashcroft Directive.

In Oregon's view, by contrast, this case is about the practice of medicine, an area of traditional state regulation. As this Court explained in *Solid Waste Agency*, an executive official is entitled to the deference petitioner claims only when Congress granted that official authority

[9] The petition asserts without qualification, for example, that the Attorney General's decision about whether a particular use, apparently *any* particular use, of a controlled substance is a "legitimate medical" use is binding on every State. Pet. Cert. 17.

to act in the arena in question. 531 U.S. at 172-73. And while Congress has granted the Attorney General broad authority over controlled substances, the CSA lacks any suggestion that it intended to appoint the Attorney General as a national medical review board, with general authority to re-determine the validity of every prescription that conforms to state law.

Thus, *Solid Waste Agency* holds that the proper inquiry begins a step earlier than the Attorney General would have it. Because this case is about regulating the practice of medicine, an area traditionally and historically within the States' regulatory powers, the starting point is to ask whether the CSA contains a clear statement of Congressional intent to allow the Attorney General to displace that traditional power. Petitioner's predecessor in office, the District Court, and the Court of Appeals all concluded that it does not. That is, each concluded that the CSA simply lacks the "clear statement" of Congressional intent that would be necessary to grant the Attorney General authority to alter the existing balance of state and federal power inherent in the recognition that regulating the practice medicine has always been a matter for the States. And in the absence of that clear statement, petitioner has no legitimate claim to deference.

The Attorney General's claim to deference in this case also ignores at least one significant aspect of the CSA. When originally enacted, the CSA provided that the Attorney General was *required* to register a physician if that physician "is authorized to dispense drugs * * * under the law of the State in which he practices." *Moore*, 432 U.S. at 140. Congress amended the CSA in 1984 to

authorize the Attorney General to deny or revoke a registration found to be contrary to the "public interest." 21 U.S.C. § 823(f). As the Court of Appeals correctly explained, the 1984 amendments to the CSA were not intended to broaden the Attorney General's authority by permitting him to sanction physicians whose conduct conformed to state laws. Pet. App. 19a-20a (quoting S. Rep. No. 98-225, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. at 3449). Rather, Congress intended only to respond to the ineffectiveness of some state licensing boards, which were failing to act against physicians who violated state laws. *See* S. Rep. No. 98-225 at 260-62, *reprinted* in 1984 U.S.C.C.A.N. at 3442-44. In other words, Congress did not intend to authorize the Attorney General to sanction physicians whose conduct was consistent with state law; it intended only to permit him to act where state regulators failed to revoke the licenses of those who violated those state laws. [10]

a. That regulating the practice of medicine is within the scope of the States' historic police powers is hardly open to debate. "Because these are primarily, and historically,

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[10] Moreover, the "legitimate medical purpose" regulation, 21 C.F.R. § 1306.04(a) (1971), was written when the CSA expressly required the Attorney General to defer to state regulators and register any physician licensed by a State to dispense controlled substances. 21 U.S.C. § 821(f) (1970). Reliance on that regulation as a source of authority to override state regulators, therefore, seems particularly suspect; when that regulation was originally enacted, it necessarily could not have been viewed as a source of authority to sanction physicians who acted in accordance with state law.

matters of local concern, the States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 475 (1996) (citations, internal quotation marks, ellipses, and brackets omitted); *accord Hill v. Colorado*, 530 U.S. 703, 715 (2000). The Attorney General's only counter-argument is to assert that "there *is* no tradition" of States permitting physicians to aid competent, terminally-ill adults to choose the manner of their own impending death. Pet. Cert. 21, *citing Glucksberg* (emphasis by petitioner). But that poses the question at the wrong level of generality. Nothing in this Court's cases suggests that the proper question is whether the specific case, matter, or practice is within the States' historic powers. Rather, the Court has consistently protected state prerogatives in "traditionally sensitive *areas*." *Will*, 491 U.S. at 65 (emphasis added). In other words, the petition offers no support for its implicit assertion that a State's choice to exercise, or decline to exercise, its police powers in an unusual, or even unprecedented, manner takes that choice out of the historic realm of state power.

b. That the CSA does not contain a "clear statement" of intent to authorize the Attorney General to determine what uses state-licensed doctors may make of substances that concededly have approved medical uses should not be controversial either. The few scraps of the CSA's text the Attorney General cited in the Court of Appeals are absent from the petition filed in this Court. Instead, the petition relies upon generalizations about the Act's structure; the unremarkable assertion that the Attorney General's decisions establish national standards when he ex-

ercises authority Congress clearly has assigned to him; and an inapposite attempt to compare this case to *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), and *Raich v. Ashcroft*, 352 F.3d 122 (9th Cir. 2003), *cert. granted* 124 S. Ct. 2909 (2004), both of which involve an express Congressional determination that marijuana has no accepted medical uses. Pet. Cert. 13-16, 26.[11]

The Attorney General also purports to find support for his claims about the statute's meaning in *United States v. Moore*, in which, he asserts, this Court concluded that the CSA intended to define a uniform national standard for the use of controlled substances in medical care. Pet. Cert. 17-18 and n. 5. But the question presented in *Moore* was not whether Congress intended to displace the States' police powers to regulate the practice of medicine.[12] While the Court did note the District Court's jury instruction that referred to medical practice

[11] The Attorney General also asserts, emphatically but without supporting authority or analysis, that the use of controlled substances authorized by the DWDA "*is* drug abuse." Pet. Cert. 23 (emphasis by petitioner). That assertion cannot be squared with Congress' description in the CSA of drug abuse as resulting from a drug's "stimulant, depressive, or hallucinogenic effect on the central nervous system." 21 U.S.C. § 811(f).

[12] The Court described the question presented in *Moore* as "whether persons who are registered under the [CSA], 21 U.S.C. § 801 *et seq.*, can be prosecuted under § 841 for dispensing or distributing controlled substances." 423 U.S. at 124.

"generally recognized and accepted in the United States," 423 U.S. at 139, Dr. Moore was prosecuted in the United States District Court for the District of Columbia. *See United States v. Moore*, 505 F.2d 426 (D.C. Cir. 1974). Consequently, there was no state law to apply. Thus, it appears to be a significant overstatement to contend that the Court's opinion in *Moore* means that Congress intended to establish "a national standard for professional practice under the CSA." Pet. Cert. 18, n 5.

3. This Court already has determined how disputes like this one—disputes over whether this case is about federal authority over controlled substances or about state authority over the practice of medicine—must be resolved. The Court has explained that where federal administrative action pushes the boundaries of Congressional power and alters the traditional state-federal balance, Congress must address the precise question at issue before the Court will defer to that administrative action. *Solid Waste Agency*, 531 U.S. at 172-73. And even where Congress includes an express preemption provision—as opposed to the express disclaimer of preemptive intent contained in the CSA[13]—the Court seeks out the "domain *expressly*

[13] Title 21, section 903, of the United States Code states:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of

pre-empted" by the specific language Congress chose, *Medtronic, Inc.*, 518 U.S. at 484 (emphasis added; internal quotation marks omitted); it does not assume that the mere inclusion of such a clause reflects Congressional intent to pre-empt in every respect. *Id.* at 485. Presuming that Congress did not intend to pre-empt state police power regulations "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Ibid.* In other words, it is insufficient for a federal official merely to point to his or her general authority, such as the Attorney General's generalized authority over enforcement of controlled substance laws, when the exercise of that authority would displace traditional state powers such as regulating the practice of medicine. Something much more specific than anything in the CSA—such as a clear statement that Congress intended to give the Attorney General authority to displace state regulations about what specific uses may be made of controlled substances that admittedly have beneficial medical uses, or that it intended to prevent the use of controlled substances for purposes authorized by the DWDA—would be required here.[14]

4. In sum, the petition offers slight support for its assertion that the Court of Appeals has overturned the federal

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this subchapter and that State law so that the two cannot consistently stand together.

[14] Congress twice attempted and twice failed to enact laws that expressly would have pre-empted the DWDA. H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998"); H.R. 2260, 106th Cong. (1999) ("Pain Relief Promotion Act of 1999").

structure or even that the court's opinion is open to serious question, and there appears to be little reason why this Court should grant review here. Although the opinion of the Court of Appeals sparked a dissent, the majority's resolution does not conflict with any decision of any other circuit. Although Oregon and the Attorney General disagree about the proper starting point for the analysis in this case, this Court has resolved that question and the disagreement here does not affect any other State or any other federal statute. Although the division of responsibilities between the state and national governments is a matter of continuing and vital interest in our federal system, the question presented by this case is hardly unique and involves nothing more than the application of settled principles. And although the policy choice underlying the DWDA is unquestionably both pioneering and controversial, that choice is not at issue in this case.

CONCLUSION

This Court should deny the petition for a writ of certiorari.

Respectfully submitted,

HARDY MYERS
Attorney General of Oregon
PETER SHEPHERD
Deputy Attorney General
MARY H. WILLIAMS
Solicitor General
ROBERT M. ATKINSON
Assistant Attorney General
Counsel for Respondents

January 10, 2005

Office of the Attorney General
Washington, D.C. 20530

June 5, 1998

The Honorable Henry J. Hyde
Chairman
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request concerning the question whether the Department of Justice, through the Drug Enforcement Administration ("DEA"), may invoke the Controlled substances Act ("CSA"), 21 U.S.C. §§ 801-971, to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act." Oreg. Rev. Stat. §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

The Oregon Act was approved by Oregon voters on November 8, 1994, and went into effect on October 27, 1997. The Act provides for a detailed procedure by which a mentally competent, terminally ill patient may

request to end his or her life "in a humane and dignified manner." O.R.S. § 127.805. The procedure requires, for example, that the patient's competence and the voluntariness of the request be documented in writing and confirmed by two witnesses, see id. § 127.810(1), that the patient's illness and competence and the voluntariness of the request be confirmed by a second physician, see id. § 127.820, and that the physician and patient observe certain waiting periods, see id. §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient's attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

Prior to the Oregon act's taking effect last year, you wrote to DEA Administrator Thomas Constantine seeking the DEA's view as to whether delivering, distributing, dispensing, prescribing, or administering a controlled substance with the intent of assisting in a suicide would violate the CSA notwithstanding a state law such as the Oregon Act. In response, Administrator Constantine explained that "physician-assisted suicide would be a new and different application of the CSA," and that the determination whether to pursue adverse action under the CSA would first require "a medico-legal investigation" involving "state and local law enforcement agencies and prosecutors." He also stated, however, that "the activities that you described in your letter to us would be, in our opinion, a violation of the CSA." Subsequently, many

other Members of Congress have sent letters urging that I support the DEA's conclusions and enforce federal laws and regulations accordingly. I have received other correspondence supporting a contrary conclusion.

The Department has conducted a thorough and careful review of the issue of whether the CSA authorizes adverse action against a physician who prescribes a controlled substance to assist in a suicide in compliance with Oregon law.

The CSA is a complex regulatory scheme that controls the authorized distribution of scheduled drugs. Physicians, for example, are authorized to prescribe and distribute scheduled drugs only pursuant to their registration with the DEA, and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The relevant provisions of the CSA provide criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. § 802(21), see id. § 841(b), and provide for revocation of the DEA drug registrations of physicians who have engaged either in such criminal conduct or in other "conduct which may threaten the public health and safety," id. § 823(f). Because these terms are not further defined by the statute, we must look to the purpose of the CSA to understand their scope.

The CSA was intended to keep legally available controlled substances within lawful channels of distribution and use. See S. Rep. No. 91-613, at 3 (1969). It sought to prevent both the trafficking in these substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress intended to prevent was that deriv-

ing from the drug's "stimulant, depressant or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f).

There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regulating the practice of medicine that involves legally available drugs (except for certain specific regulations dealing with the treatment of addicts, see 42 U.S.C. § 257a; 21 C.F.R. § 291.505).

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide, Washington v. Glucksberg, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances. If Congress had assigned DEA this role under the CSA, it would ultimately be DEA's task to determine whether assistance in the commission of a suicide, in compliance with a state law specifically permitting and regulating such assistance, nevertheless falls outside the legitimate practice of medicine and is inconsistent with the public interest. These questions, however, are not susceptible of scientific or factual resolution, but rather are fundamental questions of morality and public policy. Such a mission falls well beyond the purpose of the CSA.

The state of Oregon has reached the considered judgment that physician-assisted suicide should be au-

thorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we have concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law. We emphasize that our conclusion is limited to these particular circumstances. Adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA.

Finally, notwithstanding our interpretation of the CSA as it applies to the Oregon Act, it is important to underscore that the President continues to maintain his longstanding position against assisted suicide and any Federal support for that procedure. This position was recently codified when he signed the Assisted Suicide Funding Restriction Act last year. While states ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex but extremely important issue.

/s/ Janet Reno
Janet Reno

cc: The Honorable John Conyers, Jr.
Ranking Minority Member

(6)

No. 04-623

Supreme Court, U.S.
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IN THE

United States Supreme Court

JOHN ASHCROFT, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Petition For A Writ of Certiorari
To United States Court of Appeals for the Ninth Circuit

PATIENT-RESPONDENTS' BRIEF IN OPPOSITION

Nicholas W. van Aelstyn
Counsel of Record
Aaron S. Jacobs
Charles W. Burk
HELLER EHRMAN WHITE
& MCAULIFFE LLP
333 Bush Street
San Francisco, California 94104-2878
Telephone: 415-772-6000
Facsimile: 415-772-6268

Kathryn L. Tucker
COMPASSION & CHOICES
1201 Third Avenue, 40th Floor
Seattle, Washington 98101-3000
Telephone: 206-367-2134
Facsimile: 206-583-8500

Counsel for Patient-Respondents

QUESTION PRESENTED

Exercising its traditional police powers, Oregon enacted a law that allows physicians to prescribe and pharmacists to dispense Schedule II controlled substances to competent, terminally-ill adults who may use them under strictly regulated conditions to choose the time, place, and manner of their impending deaths. In enacting and amending the Controlled Substances Act (CSA), did Congress clearly authorize the Attorney General to determine that physicians and pharmacists acting in accordance with Oregon law have violated the CSA?

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States; Karen Tandy, Administrator of the Drug Enforcement Administration; Kenneth W. McGee, Assistant Special Agent-in-Charge of the Portland Office of the Drug Enforcement Administration; the United States of America; the United States Department of Justice; and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, David Malcolm Hochhalter, John Doe #1 and Don W. James.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	1
STATUTES AND REGULATIONS INVOLVED	2
STATEMENT OF THE CASE	2
REASONS FOR DENYING THE PETITION	6
I. Introduction	6
II. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference.	7
A. Ashcroft's Interpretation of the CSA Is Not Entitled to Heightened Deference	8
1. The *Mead* and *Barnhart* factors require *Skidmore* respect, rather than *Chevron* deference	9
2. Ashcroft's interpretation is entitled to little respect under *Skidmore*	13

Page

B. Ashcroft's Interpretation of § 1306.04 Is Not Entitled to *Seminole Rock* Deference..... 15

III. Petitioners' Contention That the Directive Sets Forth the "Prevailing Views" of Physician-Assisted Dying Is Unsupported and Unsupportable..... 18

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying..... 19

B. The Data Regarding Oregon's Experience with the ODWDA Demonstrate That Legal Physician-Assisted Dying Poses No Threat to Public Health..... 20

CONCLUSION..... 23

TABLE OF AUTHORITIES

Cases *Page*

Alaska Dept. of Environmental Conservation v. EPA, 540 U.S. 461, 124 S. Ct. 983 (2004)..... 10

Barnhart v. Walton, 535 U.S. 212 (2002)..... 9, 10

Bedford County Mem'l Hosp. v. HHS, 769 F.2d 1017 (4th Cir. 1985)..... 13

Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945)..... 15, 17

Caruso v. Blockbuster-Sony Music Entertainment Centre, 193 F.3d 730 (3d Cir. 1999)..... 16

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)..... 8, 10

Christensen v. Harris County, 529 U.S. 576 (2000)..... 10

Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261 (1990)..... 3

Dubois v. U.S. Dep't of Agriculture, 102 F.3d 1273 (1st Cir. 1996)..... 12

Gardebring v. Jenkins, 485 U.S. 415 (1988)..... 15

Hall v. U.S. EPA, 273 F.3d 1146 (9th Cir. 2001)..... 14, 17

Humphreys v. DEA, 96 F.3d 658 (3d Cir. 1996)..... 13

Page

In re Sang-Su Lee,
277 F.3d 1338 (Fed. Cir. 2002) 12

James v. Von Zemenszky,
301 F.3d 1364 (Fed. Cir. 2002) 9

Lee v. Harcleroad,
522 U.S. 927 (1997)..... 3

Lee v. Oregon,
869 F. Supp. 1491 (D. Or. 1994)..... 2

Lee v. Oregon,
891 F. Supp. 1429 (D. Or. 1995)..... 2

Lee v. Oregon,
107 F.3d 1382 (9th Cir. 1997)..... 2

Martin v. Occupational Safety and Health Review Comm'n, 499 U.S. 144 (1991) 10

Menorah Med. Ctr. v. Heckler,
768 F.2d 292 (8th Cir. 1985)..... 13

Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Auto Insurance, 463 U.S. 29 (1983)..... 12

NLRB v. Brown,
380 U.S. 278 (1965)..... 15

Norfolk S. Railway v. Shanklin,
529 U.S. 344 (2000)..... 17

Olenhouse v. Commodity Credit Corp.,
42 F.3d 1560 (10th Cir. 1994)..... 13

Page

Oregon v. Ashcroft,
192 F. Supp. 2d 1077 (D. Or. 2002) 1, 5, 14, 18

Oregon v. Ashcroft,
368 F.3d 1118 (9th Cir. 2004) 1, 3, 4, 5

Pacific Coast Fed'n of Fishermen's Ass'n, Inc. v. Nat'l Marine Fisheries Serv.,
265 F.3d 1028 (9th Cir. 2001)..... 12

Puerto Rico Higher Educ. Assistance Corp. v. Riley, 10 F.3d 847 (D.C. Cir. 1993)..... 13

Sierra Club v. Martin,
168 F.3d 1 (11th Cir. 1999) 12

Skidmore v. Swift & Co.,
323 U.S. 134 (1944)..... 8, 14

Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers,
531 U.S. 159 (2001)..... 17

St. James Hospital v. Heckler,
760 F.2d 1460 (7th Cir. 1985)..... 13

Texas Office of Pub. Util. Counsel v. FCC,
265 F.3d 313 (5th Cir. 2001), *cert. denied*
535 U.S. 986 (April 15, 2002) 12

Thomas Jefferson Univ. v. Shalala,
512 U.S. 504 (1994)..... 15, 17

United States v. Mead Corp.,
533 U.S. 218 (2001)..... 9, 10

United States v. Oakland Cannabis Buyers' Coop,
532 U.S. 483 (2001)..... 14

Page

Washington v. Glucksberg,
521 U.S. 702 (1997) 3, 19

Statutes and Regulations

21 U.S.C. § 811(b) 11

36 Fed. Reg. 4948 (1971) 16

36 Fed. Reg. 7777 (1971) 16

36 Fed. Reg. 7799 (1971) 16

66 Fed. Reg. 56,607 (2001) 5

Or. Rev. Stat. § 127.865 20

S. Rep. No. 105-372, 105th Congress,
2d Session (1998) 4

S. Rep. No. 106-299, 106th Congress,
2d Session (2000) 4

Miscellaneous

Quill, Timothy E. MD; Cassel, Christine K. MD,
Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality, Annals of Internal Medicine,
Vol. 138(3), (2003) 19-20

Lunge, R.; Royle, M.; Slater, M.; Legislative Council, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes* (2004), found at: http://www.leg.state.vt.us/reports/04Death/ Death_With_Dignity_Report.html 20, 22

Page

Fifth Annual Report on Oregon's Death with Dignity Act, Department of Human Services, Office of Disease Prevention and Epidemiology, March 6, 2003 21

Sixth Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2004 21

IN THE

Supreme Court of the United States

No. 04-623

JOHN ASHCROFT, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Petition For A Writ of Certiorari
From the United States Court of Appeals for the Ninth Circuit

PATIENT-RESPONDENTS' BRIEF IN OPPOSITION

OPINIONS BELOW

The opinion of the Court of Appeals, Pet. App. 1a-63a, is reported at *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004). The opinion of the District Court, Pet. App. 64a-97a, is reported at *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002).

STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004. Pet. App. 98a-99a. The petition for a writ

of certiorari was filed on November 9, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

Certain provisions of the Controlled Substances Act ("CSA") Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. §§ 801 *et seq.*), and a regulation promulgated thereunder, 21 C.F.R. § 1306.04, are set out in the Petitioner's Appendix at Pet. App. 149a-161a. Certain provisions of the Oregon Death with Dignity Act ("ODWDA") are set out in the Petitioner's Appendix at Pet. App. 162a-165a.

STATEMENT OF THE CASE

Patient-Respondents[1] adopt, for the purpose of this opposition to the petition for certiorari, Respondent State of Oregon's Statement of the Case.

Oregon voters approved the Oregon Death With Dignity Act ("ODWDA") on November 8, 1994. On November 23, 1994, opponents of the measure filed suit in federal court, alleging that the ODWDA violated their constitutional and statutory rights. *See Lee v. Oregon*, 869 F. Supp. 1491, 1493 (D. Or. 1994). The district court agreed and enjoined the ODWDA, *id.* at 1503 (granting preliminary injunction); *Lee v. Oregon*, 891 F. Supp. 1429 (D. Or. 1995) (granting permanent injunction), but in February of 1997 the Court of Appeals dismissed the complaint. *Lee v. Oregon*, 107 F.3d 1382, 1386 and 1392 (9th Cir. 1997).

[1] The "Patient-Respondents" are Respondents John Doe #1 and Don W. James.

Four months later, on June 27, 1997, this Court issued its decision in *Washington v. Glucksberg*, 521 U.S. 702 (1997), wherein the Court concluded:

> Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.

Id. at 735. Concurring with the Court, Justice O'Connor explained:

> There is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure. . . . [T]he . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the "laboratory" of the States . . . in the first instance.

Id. at 737 (O'Connor, J., concurring) (quotation marks omitted) (quoting *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 292 (1990) (O'Connor, J. concurring)). Shortly thereafter, this Court denied the *Lee* plaintiffs' petition for certiorari. *Lee v. Harcleroad*, 522 U.S. 927 (1997).

On November 4, 1997, after three years of litigation, the citizens of Oregon once again voted on the ODWDA, reaffirming their support for it by a margin of 60%. *See* Official Results State Measure 51 Nov. 4, 1997 State Wide Special Election at: http://www.sos.state.or.us/elections/nov497/other.info/m51abst.html. *See also Oregon v. Ashcroft*, 368 F.3d at 1122, Pet. App. at 6a-7a.

In response to requests by members of Congress in late 1997, including then-Senator Ashcroft, Attorney General Reno analyzed the question of whether practitioners acting in accordance with the ODWDA contravened the CSA. On June 5, 1998, Reno issued her interpretation of the CSA:

> The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

Letter from Reno to Hyde (June 5, 1998), Opp. App. at 50a. Reno explained that "[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." *Id.*, Opp. App. at 52a.

Later that year the ODWDA's Congressional opponents, again including then-Senator Ashcroft, introduced the Lethal Drug Abuse Prevention Act of 1998 (the "LDAPA"), *see* S. Rep. No. 105-372, *Lethal Drug Abuse Prevention Act*, 105th Congress, 2d Session (1998), but it failed to reach the floor of the House or the Senate. *See* H.R. 4006 and S. 2151, 105th Congress (1998). They then introduced the Pain Relief Promotion Act of 1999 (the "PRPA"). *See* S. Rep. No. 106-299, *The Pain Relief Promotion Act*, 106th Congress, 2d Session (2000). The PRPA passed the House in 1999 and made it out of the Senate Judiciary Committee in 2000, but failed to reach a vote on the floor of the Senate. *See* H.R. 2260 and S. 1272, 106th Congress (1999). *See also Oregon v. Ashcroft*, 368 F.3d at 1123 n.4, Pet. App. at 7a-8a. Both the LDAPA and the

PRPA would have expanded the scope of the CSA to nullify the ODWDA. Both failed.

In November of 2000, the citizens of Missouri voted Senator Ashcroft out of office. President Bush then appointed him to be the Attorney General. Understandably concerned, Oregon's Attorney General wrote to Ashcroft, asking that Oregon be consulted in the event that the Department of Justice decided to reconsider the ODWDA. Letter from Hardy Myers, Oregon Attorney General, to John Ashcroft, United States Attorney General (February 2, 2001), Opp. App. at 55a. In response, Ashcroft stated that he "would be happy to include [Oregon's] views" if he ever revisited the matter. Letter from Lori Sharpe, Director and Advisor to the U.S. Attorney General, to Hardy Myers, Oregon Attorney General (April 17, 2001), Opp. App. at 58a.

However, on November 6, 2001, without even notifying Oregon, Ashcroft announced that he had reversed his predecessor's decision. Under his new interpretation of the CSA—even without passage of the LDAPA or the PRPA—prescribing controlled substances under the ODWDA is a violation of the CSA and will result in the revocation of a practitioner's license. *See* 66 Fed. Reg. 56,607 (November 9, 2001), Pet. App. at 100a. Respondents then filed this action. The District Court permanently enjoined the Ashcroft Directive, *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002), Pet. App. at 64a, and the Court of Appeals affirmed, *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), Pet. App. at 1a. This petition followed.

REASONS FOR DENYING THE PETITION

I. Introductio.

The petition seeks review of a decision that rests upon a straightforward and narrow statutory interpretation of the Controlled Substances Act. That decision presents no split among the circuits, and, despite petitioner's best efforts, no constitutional issues.[2] For these reasons alone review is not warranted.

In addition, the petition rests on several clearly incorrect contentions in an effort to call the decision into question. This is especially clear with respect to two contentions that lie at the heart of the petition:

> There can be no question, then, that the Attorney General's interpretive ruling [1] is consistent with the prevailing views regarding medical practice and [2] on that basis is, at the very least, reasonable and entitled to deference.

Pet. at 13. Both statements are clearly and demonstrably wrong, yet they constitute a critical basis of the petition. Indeed, petitioner demands deference from this Court at the outset, claiming *Chevron* deference and more for the Attorney General's interpretation of what constitutes a "legitimate medical practice." Pet. at 11-12.

While one may or may not agree with petitioner's views on physician-assisted dying—an issue that is deeply personal, highly sensitive and controversial—to contend that

[2] Petitioner's deeply flawed constitutional arguments are addressed in the brief of Respondent State of Oregon. Patient-Respondents therefore do not address this aspect of the petition and instead join the State of Oregon's Opposition.

they are nigh-universal and thus "the prevailing views" is simply wrong. Petitioner's bold assertions ignore the record in this case and the wider reality. There is, in fact, a robust debate across the nation about empowering dying patients to control the time and manner of death, and thereby avoid protracted and intolerable suffering, by obtaining medications from their physicians which they can self-administer to bring about a humane and peaceful death.

To assert that the Attorney General's (mis)characterization of the prevailing views of medical practice is entitled to great deference compounds the error. The relevant authorities make clear that Ashcroft's unilateral assertion of executive power overriding the intent of Congress, the will of the people of Oregon, the guidance of this Court in *Glucksberg*, and the wealth of data from both the medical community and the wider society, is not entitled to deference. That petitioner should make such strained arguments demonstrates his desperation to manufacture issues worthy of the attention of this Court. He has failed to do so on each of these core issues—that of the profound questions regarding dying and modern medicine that lie at the heart of this dispute, and that of the question of how much power is accorded to the executive alone in our federal system.

II. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference.

Petitioner contends that the Court of Appeals erred by failing to accord Ashcroft's Directive proper deference. Yet he provides no support for this bold assertion of executive power.

An agency's action is subject to separate standards of review depending upon whether it is interpreting a statute or its own regulation. Some actions implicate both, as here. Although Ashcroft stated that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," Pet. App. at 102a, Section 1306.04 has nothing to do with suspending a health care provider's DEA registration. As such, Ashcroft turned to the CSA itself: "Such conduct by a physician . . . may render his registration . . . subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4)." *Id.* (quotation marks omitted).

A. Ashcroft's Interpretation of the CSA Is not Entitled to Heightened Deference.

An agency's interpretation of a statute is generally entitled to one of two levels of deference—either the higher level of deference laid out by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or the lower level of respect described in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Until petitioning this Court, Ashcroft did not claim *Chevron* deference; he expressly relied upon *Skidmore* below. *See, e.g.*, Br. for Appellants, 2002 WL 32157019 at 22 and 38-40 (Sept. 23, 2002). Notably, although petitioner demands *Chevron* deference in Section I.A.1 of the petition, he does not actually conduct a *Chevron* analysis or even argue for respect under *Skidmore*. *See* Pet. at 11-13. Rather, petitioner simply cites the standard-setting cases and assumes that the courts must accord the Directive deference. This is improper.

As a threshold matter, an agency's interpretation of a statute is entitled to *Chevron* deference only if it "appears

that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). If an agency passes the first test,[3] it still must establish the right to *Chevron* deference rather than *Skidmore* respect. This Court's recent decisions in *Barnhart v. Walton*, 535 U.S. 212 (2002), and *Mead* identified the factors used to select between these two standards. In particular, a court should consider: (1) the formality of interpretation; (2) the interstitial nature of the legal question; (3) the expertise of the agency; (4) the importance of the question to the administration of the statute; (5) the complexity of that administrative scheme; (6) the care of consideration; (7) the duration of consideration; and (8) the consistency of interpretation. *See Barnhart*, 535 U.S. at 222; *Mead*, 533 U.S. at 231-34; *see also James v. Von Zemenszky*, 301 F.3d 1364 (Fed. Cir. 2002) (discussing same). Petitioner neither engaged in an analysis of these factors nor even cited *Barnhart* or *Mead*. Their absence is not surprising, however, as each of the factors point towards *Skidmore's* lesser level of respect.

1. The *Mead* and *Barnhart* factors require *Skidmore* respect, rather than *Chevron* deference.

First, as *even petitioner admits*, the Ashcroft Directive is an "interpretive rule." *See* Pet. at 7 ("On November 9, 2001, the Attorney General published an interpretive rule . . . ."). *Chevron* deference is normally withheld from infor-

[3] Petitioner simply assumes that he has such power. State of Oregon's Opposition correctly explains why this is not the case. However, for the purposes of the following discussion, it may be assumed that he does possess such authority.

mal agency actions such as interpretive rulings. *Barnhart*, 535 U.S. at 222. As this Court explained, interpretive rules

> are not entitled to the same deference as norms that derive from the exercise of [an agency's] delegated lawmaking powers. Instead, interpretations contained in formats such as opinion letters are 'entitled to respect' under [the] decision in *Skidmore v. Swift & Co.*, but only to the extent that those interpretations have the power to persuade.

Christensen v. Harris County, 529 U.S. 576, 587 (2000) (quoting *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991)) (citations and quotation marks omitted).[4] While discussing this provision, this Court noted in *Mead* that "the overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication." *Mead*, 533 U.S. at 230 n.12. Indeed, just last year this Court again refused to apply *Chevron* deference in a situation similar to the one here. *Alaska Dept. of Environmental Conservation v. EPA*, 540 U.S. 461; 124 S. Ct. 983, 1001 (2004) (holding that an EPA "internal guidance memoranda . . . does not qualify for the dispositive force described in *Chevron*") (citing *Christensen*, 529 U.S. at 587, and *Mead*, 533 U.S. at 234).

Second, the Ashcroft Directive was hardly an attempt to fill an interstitial gap. Unlike in *Barnhart*, the Ashcroft Directive does not plug a small hole in a regulatory scheme. *Barnhart*, 535 U.S. at 214-215, 223-224 (accepting the

[4] *See also Mead*, 533 U.S. at 232 ("[I]nterpretive rules . . . enjoy no *Chevron* status as a class."). *Chevron* itself explained that it applied only to "legislative regulations." *Chevron*, 467 U.S. at 844.

Social Security Administration's definitions of "inability" and "expected to last," notwithstanding the informal method used to arrive at those definitions).

Third, the Department of Justice lacks expertise in the medical field. In fact, in passing the CSA Congress specifically denied the Attorney General the power to make medical or scientific decisions with regards to drug control within the United States. Instead, Congress placed responsibility for making such decisions in the Department of Health and Human Service:

> The Attorney General shall, before initiating proceedings [to Schedule a drug], request from the Secretary [of Health and Human Services] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled . . . . *The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.*

21 U.S.C. § 811(b), Opp. App. at 1a. Congress certainly did not intend to grant the Attorney General the power to decide what constitutes a legitimate medical practice if it withheld the authority to make medical or scientific decisions as to the scheduling of drugs.

Fourth, the ODWDA is of no importance to the administration of the CSA, which Congress intended to prevent drug trafficking and diversion. As the courts' exhaustive analyses below have made clear, the CSA was not intend-

ed to address the situations covered by the ODWDA. Pet. App. at 13a-14a & n.7; Pet. App. at 89a-92a.

Fifth, the CSA's administrative scheme has been made no more complex by protecting Oregon's physicians from prosecution when assisting in hastening humanely the deaths of competent, terminally ill patients in accordance with the ODWDA. Under the Ashcroft Directive it would be quite the opposite. DEA agents would be required to determine a doctor's intent, *post-facto*, whenever a patient dies after obtaining a prescription from that patient's doctor.

Sixth, the Attorney General did not consider the matter with care. The most probative evidence on the question of whether physician-assisted dying poses a threat to the public is the substantive data gathered pursuant to the ODWDA.[5] Yet this wealth of information was not cited once by either the OLC Memorandum or the Ashcroft Directive, and there are no findings or analyses anywhere in them that purport to show how this data relates to the alleged threat to the public interest. As this Court has noted, "an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem." *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983).[6]

[5] *See* Section III.B, *infra*.

[6] Many courts have heeded this ruling in striking administrative rules based upon such a lack of honest consideration. *See, e.g., In re Sang-Su Lee*, 277 F.3d 1338, 1344-45 (Fed. Cir. 2002); *Texas Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 323 (5th Cir. 2001) *cert. denied* 535 U.S. 986 (April 15, 2002); *Pacific Coast Fed'n of Fishermen's Ass'n, Inc. v. Nat'l Marine Fisheries Serv.*, 265 F.3d 1028, 1035-37 (9th Cir. 2001); *Sierra Club v. Martin*, 168 F.3d 1, 7 (11th Cir. 1999); *Dubois v. U.S. Dep't of Agriculture*, 102 F.3d 1273, 1285 (1st Cir. 1996); *Humphreys v. DEA*, 96 F.3d 658, 663 (3d Cir. 1996); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1574-75 (10th Cir. 1994); *Puerto Rico Higher Educ. Assistance Corp. v. Riley*, 10 F.3d 847, 852 (D.C. Cir. 1993); *Bedford County Mem'l Hosp. v. HHS*, 769 F.2d 1017, 1022 (4th Cir. 1985); *Menorah Med. Ctr. v. Heckler*, 768 F.2d 292, 295-96 (8th Cir. 1985); *St. James Hospital v. Heckler*, 760 F.2d 1460, 1467-68 (7th Cir. 1985).

Seventh, it is impossible to tell how long the Attorney General considered his position, as the process occurred behind closed doors.

Eighth, the Directive is inconsistent with the Attorney General's prior, definitive position. Attorney General Reno previously "concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Letter from Janet Reno, United States Attorney General, Department of Justice, to Henry J. Hyde, Chairman, Committee on the Judiciary, House of Representatives (June 5, 1998), Opp. App. at 53a. Ashcroft's interpretation is a complete and improper reversal of this position.

Thus, all of the factors laid out in *Barnhart* and *Mead* indicate that the Directive is not entitled to *Chevron* deference. At most it warrants only *Skidmore* respect.

2. Ashcroft's interpretation is entitled to little respect under *Skidmore*.

Under *Skidmore*, an agency's interpretation of a statute may be entitled to respect, but the value of this respect "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors

which give it power to persuade . . . .". *Skidmore*, 323 U.S. at 140. Ashcroft's interpretation fails each of these criteria—which petitioner did not analyze—and, as such, was given the proper amount of respect by the court below.

Ashcroft did not thoroughly consider the matter. Although Ashcroft told Oregon's Attorney General that he "would be happy to include [Oregon's] views" if he ever revisited the ODWDA, he neither informed Oregon of the reconsideration nor included its views. *See* Letter from Sharpe to Myers (April 17, 2001), Opp. App. 58a. Neither did he consider any of the data gathered during the first four years of the ODWDA's existence. This is more edict than analysis, and does not merit *Skidmore* respect.

Ashcroft's legal reasoning lacks merit. The only legal precedent cited in the Directive is *United States v. Oakland Cannabis Buyers' Coop*, 532 U.S. 483 (2001). Pet. App. at 101a (citing same). Yet petitioner entirely abandoned this authority in the district court and mentioned it only in passing in the Court of Appeals. *See Oregon v. Ashcroft*, 192 F. Supp. 2d at 1092 n.20 (citation omitted), Pet. App. at 94a. This was not surprising as *Oakland Cannabis*' sole holding was that "medical necessity is not a defense to manufacturing and distributing marijuana." 532 U.S. at 494. The doctrine of medical necessity is not at issue here, nor are Schedule I substances, and thus *Oakland Cannabis* provides no support for the Directive.

Ashcroft's interpretation is inconsistent with previous interpretations. Lastly, as noted above, Ashcroft's interpretation conflicts with that of his predecessor. *See, e.g.*, *Hall v. U.S. EPA*, 273 F.3d 1146, 1156 (9th Cir. 2001)

(refusing to defer to an "interpretation advanced [by the EPA that] does not fit with prior interpretations").

Based upon the *Skidmore* factors, petitioner's interpretation of the CSA should receive no deference and little respect.

B. Ashcroft's Interpretation of § 1306.04 Is Not Entitled to *Seminole Rock* Deference.

Just as with its power to interpret statutes, an agency's power to interpret its regulations is neither unbounded nor unchecked. Courts "are not obliged to stand aside and rubberstamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *NLRB v. Brown*, 380 U.S. 278, 291 (1965). Instead, under *Seminole Rock*, such interpretations must be struck if "plainly erroneous or inconsistent with the regulation." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). Although petitioner cites certain cases from the *Seminole Rock* line of precedent, he again simply assumes deference without analysis. *See* Pet. at 11-12.

An agency must have some regulatory scheme in mind when it promulgates a rule and may not later depart from it without promulgating new rules. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (noting that a court should not defer to an agency's interpretation where an "alternative reading is compelled by the regulation's plain language or by *other indications of the Secretary's intent at the time of the regulation's promulgation*") (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988))

(emphasis added).[7] Yet this is exactly what Ashcroft attempted to do by reinterpreting a thirty-year-old regulation to preempt the States' traditional role as the regulators of the medical profession within their borders.

In 1971, the Bureau of Narcotics and Dangerous Drugs published notice of the "Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970." *Purpose of Issue of Prescription*, 36 Fed. Reg. 4948 (1971), Opp. App. at 3a-4a. The proposed regulation included no official commentary and almost went unnoticed. The *only* public comment was summarized as follows: "The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § [1306.04] to determine the legitimacy of a prescription. The language has been revised to require knowledge." *Comments and Objections to Part 306*, 36 Fed. Reg. 7777 (1971), Opp. App. at 5a-7a. The regulation was adopted substantially unchanged and has since remained untouched and largely unconstrued. *Purpose of Issue of Prescription*, 36 Fed. Reg. 7799 (1971), Opp. App. at 8a-9a.

Neither the regulation itself nor its lone public comment even hinted at Ashcroft's expansive interpretation. If it was intended as Ashcroft later interpreted it, the proposed regulation surely would have been accompanied by agency commentaries and would have prompted hundreds of public comments from medical groups and the states.

[7] *See, e.g., Caruso v. Blockbuster-Sony Music Entertainment Centre*, 193 F.3d 730, 736-37 (3d Cir. 1999) ("An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning.") (citation omitted).

Moreover, it is rather unlikely that a shift of this magnitude in the constitutional role of the states would have been achieved by means of a single regulation routinely promulgated amidst many others. The obvious conclusion is that the Bureau did not intend to federalize the field of medicine. Ashcroft's interpretation of § 1306.04 is unreasonable. *Thomas Jefferson University*, 512 U.S. at 512.

Lastly, the Ashcroft Directive warrants no deference because it is contrary to Attorney General Reno's 1998 interpretation of the same regulation. *Norfolk S. Railway v. Shanklin*, 529 U.S. 344, 356 (2000) (striking agency's interpretation where it was inconsistent with prior construction). As this Court recently wrote in an analogous situation, "[a]lthough generally an agency's construction of its own regulations is entitled to substantial deference, no such deference is appropriate here. Not only is the [agency's] interpretation inconsistent with the text of [the regulation], but it also contradicts the agency's own previous construction . . . ." *Id.* (citation omitted).[8]

Given these faults, the Directive is "plainly erroneous [and] inconsistent with the regulation." *Seminole Rock*, 325 U.S. at 414. Ashcroft's interpretation is not entitled to *Seminole Rock* deference.

[8] *See also Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 168 (2001) (noting that the agency interpretation before the Court reversed the agency's prior interpretation of the same rule, yet the agency had "put forward no persuasive evidence that the [agency] mistook Congress' intent" the first time); *Hall*, 273 F.3d at 1156.

III. Petitioners' Contention That the Directive Sets Forth the "Prevailing Views" of Physician-Assisted Dying Is Unsupported and Unsupportable.

Notwithstanding the broad support for physician-assisted dying demonstrated in the record below, petitioner continues to proclaim that the "prevailing views" of the practice are that it is illegitimate, Pet. at 12-13, and that those who support it are "far outside the mainstream." Pet. at 26-27.[9] This premise is unsupportable and reveals petitioner's disregard for the wide range of views on this serious issue. Petitioner's studied ignorance extends even to the most clearly relevant information regarding the practice of physician-assisted dying in the United States: the data reported on Oregon's six years of experience with physician-assisted dying under the strict regulation of the ODWDA.[10] While petitioner disregards the evidence, substantial support exists for the right of terminally-ill, competent adults to control the time, place, and manner of their impending deaths through the option of physician-assisted dying. There is simply no basis to support a blanket contention that a physician assisting a dying patient's exercise of this right by prescribing medications is acting outside the bounds of legitimate medical practice.

[9] *See also* Pet. at 6-7 (relying on Memorandum for the Attorney General from the Office of Legal Counsel, June 27, 2001 ("OLC Memo"), Pet. App. at 115a-117a; *Oregon v. Ashcroft*, 192 F. Supp. 2d. at 1083-84 (stating that the OLC Memo was written without any request for or consideration of Oregon statistics or input from Oregon representatives), Pet. App. at 75a-76a.

[10] The seventh year of implementation is just concluded and a report regarding the seventh year's data will issue in February 2005.

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying.

Petitioner cites only selected portions of this Court's 1997 *Glucksberg* decision and the OLC Memo to support his contention that the "prevailing views" toward physician-assisted dying are that the practice is illegitimate. What is more, the OLC Memo itself relies almost exclusively upon incomplete and one-sided materials—namely, selected amici briefs submitted by opponents of physician-assisted dying in the *Glucksberg* case. Of course, there also were numerous amici briefs submitted in that case by those supportive of the practice. Petitioner likewise disregards the wide variety of amici that submitted briefs below in this case supporting the legitimacy of physician-assisted dying.

Petitioner disregards the support given by the citizens of Oregon that twice voted to adopt the ODWDA, choosing instead to characterize this entire polity as "far outside the mainstream." Petitioner also ignores the vast body of literature—including, most notably, everything that has happened since 1997—demonstrating that the debate concerning physician-assisted dying is vibrant and ongoing amongst the public, the health care community, and the States, as this Court predicted and encouraged. *Glucksberg*, 521 U.S. at 735. Recognizing the diversity of views within the medical community on the question, a significant number of medical associations have decided to embrace a position of "studied neutrality" on the question of legalizing physician-assisted dying.[11] Moreover, it is

[11] *See, e.g.*, Quill, Timothy E. MD; Cassel, Christine K. MD, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, Annals of Internal Medicine, Vol.

increasingly an informed debate: as more data emerges from the State of Oregon, speculation gives way to empirical evidence about the relative risks and benefits of the practice.[12]

B. The Data Regarding Oregon's Experience with the ODWDA Demonstrate That Legal Physician-Assisted Dying Poses No Threat to Public Health.

Petitioner's studied ignorance extends beyond the general to the specific: he ignores the actual data collected during Oregon's six years of experience with legal physician-assisted dying. Ashcroft's Directive simply assumed that the ODWDA harmed Oregonians without examining the facts. The Oregon data is not mentioned even once in the Directive, the OLC Memo, petitioner's briefs below, nor even in the petition for certiorari.

As required by the ODWDA, Oregon's experience with legal physician-assisted dying has been extensively documented and studied. Or. Rev. Stat. § 127.865, Opp. App. at 10a. To date, the Oregon Health Division and/or the Oregon Department of Human Service Office of Disease Prevention and Epidemiology have issued six annual reports that present and evaluate the State's experience with the

138(3) (2003), pp. 208-211 (attaching appendix listing Medical Organizations with Neutral Stance on Physician-Assisted Suicide).

[12] *See, e.g.*, Lunge, R.; Royle, M.; Slater, M.; Legislative Council, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes* (2004), found at: http://www.leg.state.vt.us/reports/04Death/ Death_With_Dignity_Report.html (2004 report to the Vermont legislature by the Vermont Legislative Council).

ODWDA.[13] These reports present the only reliable data regarding the experience of legal, regulated physician-assisted dying in America.

The data demonstrate that physician-assisted dying does not pose a threat to public health and safety. Physician-assisted dying is not being forced upon those who are uneducated, uninsured or otherwise disadvantaged, a threat that opponents of the ODWDA speculated would materialize.

Further, the data demonstrate that use of physician-assisted dying is quite limited. During the six years in which the practice has been legal in Oregon, a total of 171 Oregonians have chosen this option. Sixth Annual Report at 19, Opp. App. at 35a. The number of terminally-ill adults choosing this option in 2003 represents only one-seventh of one percent—*i.e.*, 0.14 percent—of Oregonians who died that year. *Id.* at 5, Opp. App. at 20a.

Indeed, rather than posing a risk to patients or the medical profession, the ODWDA has led to significant improvements in the care of the dying in Oregon. *Id.* at 16, Opp. App. at 32a. In the course of considering passage of a similar law, the State of Vermont reviewed the Oregon experience and concluded that "it is [quite] apparent from credible sources in and out of Oregon that the Death with Dignity Act has not had an adverse impact on end-of-life care and in all probability has enhanced the other options."

[13] *See, e.g.*, Sixth Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2004 ("Sixth Annual Report"), Opp. App. at 11a; Fifth Annual Report on Oregon's Death with Dignity Act, Department of Human Services, Office of Disease Prevention and Epidemiology, March 6, 2003, Opp. App. at 44a.

R. Lunge *et al.*, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes*, at p. 26.

In sum, the available data demonstrate that physician-assisted dying, far from posing any hazard to patients or the practice of medicine, has galvanized improvements in end-of-life care, benefiting all terminally-ill Oregonians. Petitioner ignores this data just as he ignored it when issuing the Directive. Rather than face the facts of this data and the fact that many within the medical community and the wider society hold views contrary to his own, petitioner asserts that the courts must defer to his blinkered view of the "prevailing views." Such studied ignorance warrants no deference by this Court, and thus this case does not warrant review.

CONCLUSION

The petition seeks to manufacture issues worthy of this Court's review where there are none. In doing so, it mischaracterizes the state of the debate on the profound issue of physician-assisted dying, and compounds this error by contending that the courts must defer to the Attorney General's narrow views on the subject. The first defies the facts and the second the law. The decision below is a well-reasoned and narrow construction of the CSA, and is not contrary to the decision of any other circuit. The petition for a writ of certiorari should be denied.

Respectfully submitted,

NICHOLAS W. van AELSTYN
Counsel of Record
AARON S. JACOBS
CHARLES W. BURK
HELLER EHRMAN WHITE & MCAULIFFE LLP
333 Bush Street
San Francisco, CA 94104-2878
Telephone: (415) 772-6000
Facsimile: (415) 772-6268

Counsel for Patient-Respondents

KATHRYN L. TUCKER
COMPASSION & CHOICES
1201 3rd Avenue, 40th Floor
Seattle, WA 98101-3000
Telephone: (206) 367-2134
Facsimile: (206) 583-8500

Counsel for Patient-Respondents

APPENDIX

APPENDICES

	Page
21 U.S.C. § 811(b)	1a
§ 306.04 – Purpose of issue of Prescription, 36 Fed. Reg. 4948 (March 13, 1971)	3a
Comments and Objections to Part 306, 36 Fed. Reg. 7777 (April 24, 1971).....	5a
§ 306.04 –Purpose of Issue of Prescription, 36 Fed. Reg. 7799 (April 24, 1971).....	8a
The Oregon Death With Dignity Act – Or. Rev. Stat. § 127.865.....	10a
Oregon Department of Human Services, *Sixth Annual Report on Oregon's Death with Dignity Act*, March 10, 2004; and March 16, 2004 cover letter from Hilary E. Ware submitting same to Court of Appeal for consideration	11a
K. Hedberg, M.D., M.P.H.; D. Hopkins, M.S.; M. Kohn, M.D., M.P.H.; *Five Years of Legal Physician-Assisted Suicide in Oregon*, New England Journal of Medicine, Volume 348:961-964, March 6, 2003; and March 19, 2003 cover letter from Hilary E. Ware submitting same to Court of Appeal for consideration	44a
June 5, 1998 letter from U.S. Attorney General Janet Reno to Henry J. Hyde, Chairman of Committee on the Judiciary, U.S. House of Representatives.....	50a

February 2, 2001 letter from Hardy Myers, Oregon Attorney General, to John Ashcroft, Attorney General of the United States 55a

April 17, 2001 letter from Lori Sharpe, Director and Advisor to the U.S. Attorney General, to Hardy Myers, Oregon Attorney General 58a

21 U.S.C. § 811(b)

§ 811. Authority and criteria for classification of substances

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the

drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

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VOLUME 36 • NUMBER 50

Saturday, March 13, 1971 • Washington, D.C.

PART II

Department of Justice

Bureau of Narcotics and Dangerous Drugs

•

Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970

PART 306—PRESCRIPTIONS

General Information

§ 306.04 Purpose of issue of prescription.

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person filling such a prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

FEDERAL REGISTER

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PART II

Department of Justice

Bureau of Narcotics and Dangerous Drugs

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Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970

COMMENTS AND OBJECTIONS TO PART 306

1. The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § 306.04 to determine the legitimacy of a prescription. The language has been revised to require knowledge.

2. Several pharmacy groups protested the requirement under § 306.11(c)(4) that, if a doctor fails to provide an authorization for emergency order as required, the pharmacist must so report to the Bureau or be liable for dispensing a substance in schedule II without a written prescription. The Director considered the problems and concluded that only this mechanism assures information to the Bureau about doctors who refuse to comply with the Act.

3. The American Pharmaceutical Association and the National Association of Chain Drug Stores suggested that, in the case of a partial filling of a schedule II substance, the pharmacist notify the doctor only when the remainder cannot be filled, in order for the doctor to issue a new prescription. The language was revised accordingly.

4. All retail druggist associations urged revision in the labeling requirements for prescriptions set forth in §§ 306.14 and 306.23. In response, the Director has had the requirements of inclusion of the patient's address and the doctor's registration number deleted.

5. In response to a comment from the National Association of Retail Druggists, a definition of prescription was added which covers all orders for medication except hospital orders (i.e., orders for medication to be administered immediately and cannot be removed from the hospital either by an out-patient or by an in-patient being dis-

charged). Sections 306.11, 306.21, and 306.31 were revised to indicate that institutional practitioners (e.g., hospitals) can only dispense by prescription or hospital order.

6. Several questions were asked about the status of paregoric. This is a schedule III substance which is not now a prescription drug under the Food, Drug and Cosmetic Act and therefore not subject to the prescription requirements of the Controlled Substances Act. Until such time as it becomes a prescription drug, the Director has determined to treat it in the same manner as a schedule V substance. Section 306.32 has been revised accordingly.

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PART II

Department of Justice

Bureau of Narcotics and Dangerous Drugs

•

Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970

§ 306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

The Oregon Death With Dignity Act
Or. Rev. Stat. § 127.865

Reporting requirements.

(1)(a) The Department of Human Services shall annually review a sample of records maintained pursuant to ORS 127.800 to 127.897.

(b) The department shall require any health care provider upon dispensing medication pursuant to ORS 127.800 to 127.897 to file a copy of the dispensing record with the department.

(2) The department shall make rules to facilitate the collection of information regarding compliance with ORS 127.800 to 127.897. Except as otherwise required by law, the information collected shall not be a public record and may not be made available for inspection by the public.

(3) The department shall generate and make available to the public an annual statistical report of information collected under subsection (2) of this section. [1995 c.3 § 3.11; 1999 c.423 §9; 2001 c.104 § 40]

[LETTERHEAD]

HELLEREHRMAN
ATTORNEYS

March 16, 2004

Hilary E. Ware
hware@hewm.com
Direct (415) 772-6459
Main (415) 772-6000
Fax (415) 772-6268

Via Hand Delivery

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Re: *State of Oregon et al., v. Ashcroft*
Case No. 02-35587

Dear Sir or Madam:

Pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure, the Patient Plaintiffs-Appellees in the above-mentioned case wish to bring to the Court's attention a significant supplemental authority that has recently been released. On March 10, 2004, the Oregon Department of

Human Services released the "Sixth Annual Report on Oregon's Death with Dignity Act," an examination of data from the sixth year of the Oregon Death With Dignity Act ("ODWDA"). The Patient Plaintiffs-Appellees cited and discussed the data contained in the reports from the first four years of the ODWDA in their Brief at pages 13-14 and 37 n. 105, and submitted the report from the fifth year by a similar request on March 19, 2003. This report should also be considered in that context.

A copy of this report is enclosed with this request, and is also available at http://www.dhs.state.or.us/publichealth/chs/pas/pas.cfm. Thank you for your consideration of this request.

Very truly yours,

/s/ HILARY E. WARE
Hilary E. Ware

cc: All Counsel of Record
Enclosures

[Letterhead bottom:]

Heller Ehrman White & McAuliffe LLP
333 Bush Street
San Francisco, CA 94104-2878
www.hewm.com

San Francisco Silicon Valley Los Angeles San Diego
Seattle Portland Anchorage New York Washington D.C.
Madison, WI Hong Kong Singapore
Affiliated Offices: Milan Paris Rome

PROOF OF SERVICE BY FACSIMILE AND U.S. MAIL

I, Gary Padilla, declare as follows:

I am employed with the law firm of HELLER, EHRMAN, WHITE & MCAULIFFE, whose address is 333 Bush Street, San Francisco, California 94104-2878. I am readily familiar with the business practices of this office for collection and processing of correspondence for mailing with the United States Postal Service and for the transmission of documents by facsimile. I am over the age of eighteen years and not a party to this action.

On March 16, 2004, I served the following document:

LETTER TO COURT CLERK RE SUPPLEMENTAL AUTHORITY PURSUANT TO RULE 28(j) OF THE FEDERAL RULES OF APPELLATE PROCEDURE

on the below party(s) in this action by transmitting by facsimile machine and by placing true copies thereof in sealed envelopes, addressed as shown, for collection and mailing pursuant to the ordinary business practice of this office which is that correspondence for mailing is collected and deposited with the United States Postal Service on the same day in the ordinary course of business:

Gregory Katsas, Esq.
Mark B. Stern, Esq.
Jonathan H. Levy, Esq.
U.S. Dept. of Justice –
Civil Division
Appellate Staff
Room 9541 PHB
601 D Street, N.W.
Washington, D.C. 20530-0001

Robert B. Rocklin
Assistant Attorney General
Appellate Division
Oregon Department of Justice
1162 Court Street NE
Salem, OR 97301-4096

Eli D. Stutsman
621 SW Morrison, 13th Floor
Portland, OR 97205

Stephen K. Bushong
Trial Division
Oregon Department of Justice
1162 Court Street, NE
Salem, OR 97301-4096

Kathryn Tucker
Compassion in Dying Federation
1201 3rd Avenue, 40th Floor
Seattle, WA 98101-3000

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed at San Francisco, California, on March 16, 2004.

/s/ GARY PADILLA
Gary Padilla

Sixth Annual Report on
Oregon's Death with
Dignity Act

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STATE OF OREGON
1859

Department of Human Services
Office of Disease Prevention and Epidemiology
March 10, 2004

[Logo]
DHS
Oregon Department
of Human Services

Sixth Annual Report on Oregon's Death with Dignity Act

For more information contact:
Darcy Niemeyer
Department of Human Services, Health Services
Office of Disease Prevention and Epidemiology
800 N.E. Oregon Street, Suite 730
Portland, OR 97232
E-mail: darcy.niemeyer@state.or.us
Phone: 503-731-4023
Fax: 503-731-4082
http://www.dhs.state.or.us/publichealth/chs/pas/pas.cfm

Contributing Editor: Richard Leman, MD
Date Analysis: David Hopkins, MS

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Table of Contents

Summary 4
Introduction 6
History 6
Requirements 7
Methods
The Reporting System 9
Data Analyses 10
Results 11
Patient Characteristics 12
Physician Characteristics 13
Lethal Medication 13
Complications 14
End of Life Concerns 14
Comments 15
References 17
Tables
Table 1 19
Table 2 21
Table 3 22
Table 4 23

SUMMARY

Physician-assisted suicide (PAS) has been legal in Oregon since November 1997, when Oregon voters approved the Death with Dignity Act (DWDA) for the second time (see *History*, page 6). The Department of Human Services (DHS) is legally required to collect information regarding compliance with the Act and make the information available on a yearly basis. In this sixth annual report, we characterize the 42 Oregonians who, in 2003, ingested medications prescribed under provisions of the Act, and look at whether the numbers and characteristics of these patients differ from those who used PAS in prior years. Patients choosing PAS were identified through mandated physician and pharmacy reporting. Our information comes from these reports, physician interviews and death certificates. We also compare the demographic characteristics of patients participating during 1998-2003 with other Oregonians who died of the same underlying causes.

In 2003, 42 physicians wrote a total of 67 prescriptions of lethal doses of medication. The number of prescriptions written increased in each of the previous years: 58 prescriptions were written in 2002, 44 in 2001, 39 in 2000, 33 in 1999, and 24 in 1998. Thirty-nine of the 2003 prescription recipients died after ingesting the medication. Of the 28 persons who did not ingest the prescribed medication, 18 died from their illnesses, and 10 were alive on December 31, 2003. In addition, two patients who received prescriptions during 2002 and another who received a prescription in 2001 died in 2003 after ingesting their medication for a total of 42 PAS deaths during 2003.

There were four more patients who used PAS in 2003 than in 2002, and the number of patients ingesting lethal

medication has increased over the six years since legalization. In 2003, 42 patients died from PAS, compared to 38 in 2002, 21 in 2001, 27 in 2000, 27 in 1999, and 16 in 1998 [1-5]. The 42 patients who ingested lethal medications in 2003 represent an estimated 14/10,000 total deaths, compared with 12.2 in 2002, 7.0 in 2001, 9.1 in 2000, 9.2 in 1999, and 5.5 in 1998. Compared to all Oregon decedents in 2003, PAS participants were more likely to have malignant neoplasms (83%), to be younger (median age 73 years), and to have more formal education (48% had at least a baccalaureate degree).

During the past six years, the 171 patients who took lethal medications differed in several ways from the 53,544 Oregonians dying from the same underlying diseases. Rates of participation in PAS decreased with age, but were higher among those who were divorced or never married, those with more years of education, and those with amyotrophic lateral sclerosis, HIV/AIDS, or malignant neoplasms (see *Patient Characteristics*, page 12).

Physicians indicated that patient requests for lethal medications stemmed from multiple concerns related to autonomy and control at the end of life. The three most commonly mentioned end-of-life concerns during 2003 were: loss of autonomy, a decreasing ability to participate in activities that made life enjoyable, and a loss of dignity (see *End of Life Concerns*, page 15).

During 2003, 37 patients (88%) used pentobarbital as their lethal medication, four patients (10%) used secobarbital, and one (2%) used secobarbital/amobarbital (Tuinal). (see *Lethal Medication*, page 14).

During 2003, complications were reported for three patients. All involved regurgitation and none involved seizures (see *Complications*, page 14). One-half of patients

became unconscious within four minutes of ingestion of the lethal medication and died within 20 minutes. The range of time from ingestion to death was five minutes to 48 hours. Emergency medical services were called by one patient's family to pronounce death; neither resuscitation nor transport was requested.

Although the number of Oregonians ingesting legally prescribed lethal medications has increased, the overall number of terminally ill patients ingesting lethal medication has remained small, with about 1/7 of one percent of Oregonians dying by physician-assisted suicide.

INTRODUCTION

This sixth annual report reviews the monitoring and data collection system that was implemented under Oregon's Death with Dignity Act (DWDA), which legalizes physician-assisted suicide (PAS) for terminally ill Oregon residents. This report summarizes the information collected on patients and physicians who participated in the Act in its sixth year of implementation (January 1, 2003 to December 31, 2003) and examines trends over the six years since legalization. Using physician reports, interviews, and death certificates, we address the following questions: Is the number of residents using legal PAS in Oregon increasing? Do patients who participated in 2003 resemble patients using PAS in previous years and other Oregonians dying from similar diseases? Have any changes occurred in the PAS process during the past six years?

History

The Oregon Death with Dignity Act was a citizen's initiative first passed by Oregon voters in November 1994 with 51% in favor. Implementation was delayed by a legal injunction, but after proceedings that included a petition denied by the United States Supreme Court, the Ninth Circuit Court of Appeals lifted the injunction on October 27, 1997. In November 1997, a measure asking Oregon voters to repeal the Death with Dignity Act was placed on the general election ballot (Measure 51, authorized by Oregon House Bill 2954). Voters rejected this measure by a margin of 60% to 40%, retaining the Death with Dignity Act. After voters reaffirmed the DWDA in 1997, Oregon became the only state allowing legal physician-assisted suicide [6].

Although physician-assisted suicide has been legal in Oregon for six years, it remains highly controversial. On November 6, 2001, US Attorney General John Ashcroft issued a new interpretation of the Controlled Substances Act, which would prohibit doctors from prescribing controlled substances for use in physician-assisted suicide. To date, all the medications prescribed under the Act have been barbiturates, which are controlled substances and therefore, would be prohibited by this ruling for use in PAS. In response to a lawsuit filed by the State of Oregon, on November 20, 2001, a US district court issued a temporary restraining order against Ashcroft's ruling pending a new hearing within 5 months. On April 17, 2002, U.S. District Court Judge Robert Jones upheld the Death with Dignity Act. In September 2002, Attorney General Ashcroft filed an appeal, asking the Ninth U.S. Circuit Court of Appeals to overturn the District Court's ruling. At this time, Oregon's law remains in effect.

Requirements

The Death with Dignity Act allows terminally ill Oregon residents to obtain and use prescriptions from their physicians for self-administered, lethal medications. Under the Act, ending one's life in accordance with the law does not constitute suicide. However, we use the term "physician-assisted suicide" because it is used in the medical literature to describe ending life through the voluntary self-administration of lethal medications prescribed by a physician for that purpose. The Death with Dignity Act legalizes PAS, but specifically prohibits euthanasia, where a physician or other person directly administers a medication to end another's life. [6]

To request a prescription for lethal medications, the Death with Dignity Act requires that a patient must be:

- An adult (18 years of age or older),
- A resident of Oregon,
- Capable (defined as able to make and communicate health care decisions),
- Diagnosed with a terminal illness that will lead to death within six months.

Patients meeting these requirements are eligible to request a prescription for lethal medication from a licensed Oregon physician. To receive a prescription for lethal medication, the following steps must be fulfilled:

- The patient must make two oral requests to his or her physician, separated by at least 15 days.
- The patient must provide a written statement to his or her physician, signed in the presence of two witnesses.

- The prescribing physician and a consulting physician must confirm the diagnosis and prognosis.
- The prescribing physician and a consulting physician must determine whether the patient is capable.
- If either physician believes the patient's judgment is impaired by a psychiatric or psychological disorder, the patient must be referred for a psychological examination.
- The prescribing physician must inform the patient of feasible alternatives to assisted suicide including comfort care, hospice care, and pain control.
- The prescribing physician must request, but may not require, the patient to notify his or her next-of-kin of the prescription request.

To comply with the law, physicians must report to the Department of Human Services (DHS) all prescriptions for lethal medications [7]. Reporting is not required if patients begin the request process but never receive a prescription. In the summer of 1999, the Oregon legislature added a requirement that pharmacists must be informed of the prescribed medication's ultimate use. Physicians and patients who adhere to the requirements of the Act are protected from criminal prosecution, and the choice of legal physician-assisted suicide cannot affect the status of a patient's health or life insurance policies. Physicians and health care systems are under no obligation to participate in the Death with Dignity Act [6].

METHODS

The Reporting System

DHS is required by the Act to develop and maintain a reporting system for monitoring and collecting information on PAS [6]. To fulfill this mandate, DHS uses a system involving physician and pharmacist compliance reports, death certificate reviews, and follow-up interviews [7].

When a prescription for lethal medication is written, the physician must submit to DHS information that documents compliance with the law. We review all physician reports and contact physicians regarding missing or discrepant data. DHS Vital Records files are searched periodically for death certificates that correspond to physician reports. These death certificates allow us to confirm patients' deaths, and provide patient demographic data (e.g., age, place of residence, level of education).

In addition, using our authority to conduct special studies of morbidity and mortality [8], DHS has conducted telephone interviews with prescribing physicians after receipt of the patients' death certificates. Each physician was asked to confirm whether the patient took the lethal medications. If the patient had taken the medications, we asked physicians for information that was not available from physician reports or death certificates—including insurance status and enrollment in hospice. We asked why the patient requested a prescription, specifically exploring concerns about the financial impact of the illness, loss of autonomy, decreasing ability to participate in activities that make life enjoyable, being a burden, loss of control of bodily functions, uncontrollable pain, and loss of dignity. We collected information on the time to unconsciousness and death, and asked about any adverse reactions. Because

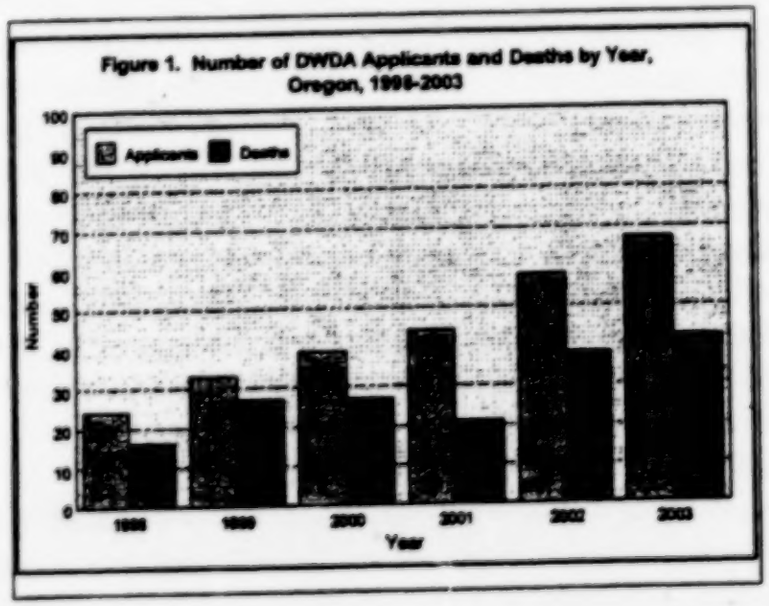
physicians are not legally required to be present when a patient ingests the medication, not all have information about what happened when the patient ingested the medication. If the prescribing physician was not present, we accepted information they had based on discussions with family members, friends or other health professionals who attended the patients' deaths. We do not interview or collect any information from patients prior to their death. Reporting forms and the physician questionnaire are available at http://www.dhs.state.or.us/publichealth/chs/pas/pasforms.cfm.

Data Analyses

We classified patients by year of participation based on when they ingested the legally-prescribed lethal medication. Using demographic information from 1997-2002 Oregon death certificates (the most recent years for which complete data are available), we compared patients who used legal PAS with other Oregonians who died from the same diseases. Demographic- and disease-specific PAS rates were computed using the number of deaths from the same causes as the denominator. The overall PAS rates by year were computed using the total number of resident deaths. Annual rates were calculated using numerator and denominator data from the same year, except for 2003 where the number of resident deaths from 2002 was used as the denominator.

RESULTS

Both the number of prescriptions written and the number of Oregonians using PAS have increased over the six years that PAS has been legal in Oregon. In 2003, 42 physicians wrote 67 prescriptions for lethal doses of medication. The number of prescriptions written has increased over the six years since legalization: 58 prescriptions were written in 2002, 44 in 2001, 39 in 2000, 33 in 1999 and 24 in 1998. Thirty-nine of the 2003 prescription recipients died after ingesting the medication. Of the 28 recipients who did not ingest the prescribed medication in 2003, 18 died from their illnesses, and 10 were alive on December 31, 2003. In addition, two patients who received prescriptions during 2002 and another who received a prescription in 2001 died in 2003, after ingesting their medication, giving a total of 42 PAS deaths during 2003 (*Figure 1*). Thirty different physicians wrote the 42 prescriptions for lethal medication.



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The number of patients ingesting lethal medication has increased over the six years since legalization. The 42 PAS deaths in 2003 compare to 38 in 2002, 21 in 2001, 27 in 2000, 27 in 1999, and 16 in 1998. The 42 patients who ingested lethal medications in 2003 represent an estimated 14/10,000 total deaths compared with 12.2 in 2002, 7.0 in 2001, 9.1 in 2000, 9.2 in 1999, and 5.5 in 1998.

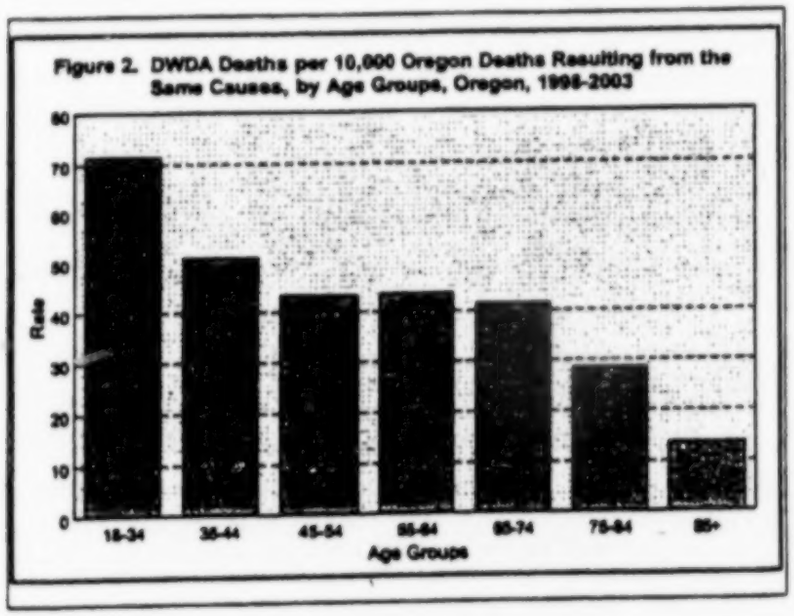
The percentage of patients referred to a specialist for psychological evaluation has declined, falling from 31 percent in 1998 to five percent in 2003.

Patient Characteristics

Oregonians using PAS during 2003 differed from those of previous years in several ways. They were more apt to be older (their median age was 73 compared to 69 for those using PAS in preceding years); they were more apt to have at least a baccalaureate degree (48% did so compared to 38% of their predecessors); and a greater proportion of patients resided in Multnomah, Clackamas, and Washington counties (45% vs. 37%). However, these figures are based on relatively few events and do not represent statistically significant differences (Table 1).

Although year-to-year variations occur, certain demographic patterns have become evident over the past six years. Males and females were equally likely to take advantage of the DWDA, but terminally ill younger persons were significantly more likely to turn to PAS than their older counterparts; 18- to 34-year-olds were 5.3 times more likely to use PAS than were those 85 or older (Table 2 and *Figure 2*). Asian Oregonians were about three times as likely to use PAS as were white Oregonians. Divorced and never-married persons were about two times more likely to use PAS

than married and widowed residents. A higher level of education was strongly associated with the use of PAS; Oregonians with a baccalaureate degree or higher were 7.6 times more likely to use PAS than those without a high school diploma. By region, residents living east of the Cascade Range were less than half as likely to use PAS as those living in western Oregon.



The type of terminal illness is a strong predictor of the likelihood of a patient using PAS (Table 3). The rates of DWDA deaths to non-PAS deaths resulting from the same causes were high for three conditions: amyotrophic lateral sclerosis (ALS) (249.0 per 10,000), HIV/AIDS (171.4), and malignant neoplasms (37.6). Among the causes associated with at least three deaths, the lowest rate (9.7) was for patients with chronic lower respiratory diseases (CLRD), such as emphysema. Persons with ALS (Lou Gehrig's disease) were more than 25 times as likely to use PAS as were those with CLRD.

During 2003, most patients died at home, but two died at assisted living residences while another died in a physician's office. All individuals had some form of health insurance (Table 4). As in previous years, most (93%) of the patients who used PAS in 2003 were enrolled in hospice care. The median length of the patient-physician relationship was ten weeks.

Physician Characteristics

The prescribing physicians of patients who used PAS during 2003 had been in practice a median of 21.5 years (range 3-35). Their medical specialties included: internal medicine (12%), oncology (38%), family medicine (45%), and other (5%).

Prescribing physicians were present while 12 (29%) of the 42 patients ingested the lethal medications. Among the remaining 30 patients, 67% ingested the medication in the presence of another health-care provider/volunteer.

During 2003, one case involving possible non-compliance with DWDA provisions regarding witnessing of signatures was reported to the Oregon Board of Medical Examiners.

Lethal Medication

During 1998-2002, secobarbital was the lethal medication prescribed for 85 of the 129 patients (66%). During 2003, 37 patients (88%) used pentobarbital, four patients used secobarbital, and one used secobarbital/amobarbital. Since the DWDA was implemented, 52% of the PAS

patients used secobarbital, 46% used pentobarbital, and 2% used other medications (mostly secobarbital/amobarbital).

Complications

During 2003, physicians reported that three patients experienced complications: a small emesis was reported for one patient who died 20 minutes after ingestion of the lethal medication. Another patient consumed about 60% of the prescribed pentobarbital, regurgitated about one-third of the medication consumed to that point, and then drank one-half of the remaining medication, dying 20 minutes later. A third patient drank one-half of the prescribed medication and about 30 seconds later regurgitated one-third of what had been consumed, retaining only about 3 grams of the barbiturate. This patient lived for 48 hours after having ingested only about one-third of the intended dose.

One physician reported that a patient fell asleep before ingesting the entire dose of medication. The patient died 40 minutes after ingestion.

None of the patients regained consciousness after ingesting the lethal medication.

Emergency medical services were contacted by a family in one case to pronounce death but not to intervene or transport the patient.

End of Life Concerns

Physicians were asked if, based on discussions with patients, any of seven end-of-life concerns might have contributed to the patients' requests for lethal medication (Table 4). In nearly all cases, physicians reported multiple concerns contributing to the request. During 2003, one patient (2%) was reported to have one end-of-life concern,

13 (31%) had two concerns, 15 (36%) had three concerns, nine (21%) had four concerns, and four (10%) had five concerns. The most frequently reported concerns included losing autonomy (93%), a decreasing ability to participate in activities that make life enjoyable (93%), and loss of dignity (82%). (The frequency of the latter concern was assessed for the first time in 2003.)

COMMENTS

During the six years since legalization, the number of prescriptions written for physician-assisted suicide and the number of terminally ill patients taking lethal medication has increased. However, the number has remained small compared to the total number of deaths in Oregon, with about 1/7 of one percent of Oregonians dying by PAS. This proportion is consistent with numbers from a survey of Oregon physicians [9]. Overall, smaller numbers of patients appear to use PAS in Oregon compared to the Netherlands [10]. However, as detailed in previous reports [1-5], our numbers are based on a reporting system for terminally ill patients who legally receive prescriptions for lethal medications, and do not include patients and physicians who may act outside the provisions of the DWDA.

Over the last six years the rate of PAS among patients with ALS in Oregon has been substantially higher than among patients with other illnesses. This finding is consistent with other studies. In the Netherlands, where both PAS and euthanasia are openly practiced, one in five ALS patients died as a result of PAS or euthanasia [11]. A study of Oregon and Washington ALS patients found that one-third of these patients discussed wanting PAS in the last month of life [12]. It is not known with certainty why ALS

patients would be more likely to choose PAS than would other terminally ill patients. Oregon HIV/AIDS patients are also disproportionately likely to use PAS, a finding consistent with studies elsewhere [13].

Physicians have consistently reported that concerns about loss of autonomy and decreased ability to participate in activities that make life enjoyable are important motivating factors in patient requests for lethal medication across all six years. Interviews with family members during 1999 corroborated physician reports [2]. These findings were supported by a recent study of hospice nurses and social workers caring for PAS patients in Oregon [14].

The availability of PAS may have led to efforts to improve end-of-life care through other modalities. While it may be common for patients with a terminal illness to consider PAS, a request for PAS can be an opportunity for a medical provider to explore with patients their fears and wishes around end-of-life care, and to make patients aware of other options. Often once the provider has addressed a patient's concerns, he or she may choose not to pursue PAS [15]. The availability of PAS as an option in Oregon also may have spurred Oregon doctors to address other end-of-life care options more effectively. In one study, Oregon physicians reported that, since the passage of the Death with Dignity Act in 1994, they had made efforts to improve their knowledge of the use of pain medications in the terminally ill, to improve their recognition of psychiatric disorders such as depression, and to refer patients more frequently to hospice [16].

REFERENCES

1. Chin G, Hedberg K, Higginson G, Fleming D. Legalized physician-assisted suicide in Oregon—The first year's experience. N Engl J Med, 1999;340:577-83.
2. Sullivan AD, Hedberg K, Fleming D. Legalized physician-assisted suicide in Oregon—The second year. N Engl J Med, 2000;342:598-604.
3. Sullivan AD, Hedberg K, Hopkins D. Legalized physician-assisted suicide in Oregon, 1998-2000. N Engl J Med, 2001;344:605-7.
4. Hedberg K, Hopkins D, Southwick K. Legalized physician-assisted suicide in Oregon, 2001. N Engl J Med, 2002;346:450-2.
5. Hedberg K, Hopkins D, Kohn M. Five years of legal physician-assisted suicide in Oregon. N Engl J Med, 2003;348:961-4.
6. Oregon Revised Statute 127.800-127.995. Available at http://www.dhs.state.or.us/publichealth/chs/pas/ors.cfm
7. Oregon Administrative Rules 333-009-000 to 333-009-0030. Available at http://www.dhs.state.or.us/publichealth/chs/pas/oars.cfm
8. Oregon Revised Statute 432.060. http://www.leg.state.or.us/ors/432.html
9. Ganzini L, Nelson HD, Schmidt TA, et al. Physicians' experiences with the Oregon Death with Dignity Act. N Engl J Med, 2000;342:557-63.

10. Willems DL, Daniels ER, van der Wal G, et al. Attitudes and practices concerning the end of life: A comparison between physicians from the United States and from The Netherlands. Arch Intern Med, 2000;160:63-8.

11. Vledink JH, Wokke JHJ, Van Der Wal G, et al. Euthanasia and physicians-assisted suicide among patients with amyotrophic lateral sclerosis in the Netherlands. N Engl J Med, 2002;346:1638-44.

12. Ganzini L, Silveira MJ, Johnston WS. Predictors and correlates of interest in assisted suicide in the final month of life among ALS patients in Oregon and Washington. J Pain Symptom Manage, 2002;3:312-7.

13. Bosshard G, Ulrich E, Bar W. 748 Cases of suicide assisted by a Swiss right-to-die organization. Swiss Med Wkly, 2003;133:310-317.

14. Ganzini L, Harvath TA, Jackson A, et al. Experiences of Oregon nurses and social workers with hospice patients who requested assistance with suicide. N Engl J Med, 2002;347:582-8.

15. Bascom PB, Tolle SW. Responding to requests for physician-assisted suicide: "these are uncharted waters for both of us . . .". JAMA, 2002;288:91-8.

14. Ganzini L, Nelson HD, Lee MA, et al. Oregon physicians' attitudes about and experiences with end-of-life care since the passage of the Oregon Death with Dignity Act. JAMA 2001;285:2363-9.

Table 1. Demographic characteristics of 171 DWDA patients who died after ingesting a lethal dose of medication, by year, Oregon, 1998-2003.

Characteristics	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Sex			
Male (%)	19 (45)	71 (55)	90 (53)
Female (%)	23 (55)	58 (45)	81 (47)
Age			
18-34 (%)	0 (0)	2 (2)	2 (1)
35-44 (%)	2 (5)	3 (2)	5 (3)
45-54 (%)	4 (10)	10 (8)	14 (8)
55-64 (%)	8 (19)	21 (16)	29 (17)
65-74 (%)	9 (21)	46 (36)	55 (32)
75-84 (%)	14 (33)	37 (29)	51 (30)
85+ (%)	5 (12)	10 (8)	15 (9)
Median years (Range)	73 (40-93)	69 (25-94)	70 (25-94)
Race			
White (%)	41 (98)	125 (97)	166 (97)
Asian (%)	1 (2)	4 (3)	5 (3)
Other (%)	0	0	0
Marital status			
Married (%)	15 (36)	60 (47)	75 (44)
Widowed (%)	12 (29)	29 (23)	41 (24)
Divorced (%)	10 (24)	32 (25)	42 (25)
Never married (%)	5 (12)	8 (6)	13 (8)
Education			
Less than high school (%)	2 (5)	14 (11)	16 (9)
HS graduate (%)	8 (19)	43 (33)	51 (30)

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Education (Cont'd)			
Some college (%)	12 (29)	23 (18)	35 (21)
Baccalaureate or higher (%)	20 (48)	49 (38)	69 (40)
Residence			
Metro counties (%)**	19 (45)	48 (37)	67 (39)
Coastal counties (%)***	3 (7)	11 (9)	14 (8)
Other W. counties (%)	19 (45)	60 (47)	79 (46)
E. of the Cascades (%)	1 (2)	10 (8)	11 (6)
Underlying illness			
Malignant neoplasms (%)	35 (83)	100 (78)	135 (79)
Lung and bronchus (%)	9 (21)	24 (19)	33 (19)
Breast (%)	6 (14)	10 (8)	16 (9)
Pancreas (%)	4 (10)	12 (9)	16 (9)
Colon (%)	3 (7)	7 (5)	10 (6)
Other (%)	13 (31)	47 (36)	60 (35)
Amyotrophic lateral sclerosis (%)	3 (7)	10 (8)	13 (8)
Chronic lower respiratory dis. (%)	1 (2)	8 (6)	9 (5)
HIV/AIDS (%)	2 (5)	1 (1)	3 (2)
Illnesses listed below (%)#	1 (1)	10 (8)	11 (6)

* Unknowns are excluded when calculating percentages.

** Clackamas, Multnomah, and Washington counties.

*** Excluding Douglas and Lane counties.

Includes aortic stenosis, congestive heart failure, diabetes mellitus with renal complications, gastrointestinal stromal tumor, myelodysplastic syndrome, pulmonary disease with fibrosis, scleroderma, and Shy-Drager syndrome.

Table 2. Demographic characteristics of 171 patients who died during 1998-2003 after ingesting a lethal dose of medication compared with 53,544 Oregonians dying from the same underlying diseases.

Characteristics	PAS patients 1998-2003 (N = 171)*	Oregon deaths, same diseases (N = 53,544)*	DWDA deaths per 10,000 Oregon deaths	Rate ratio (95% CI**)
Sex				
Male (%)	90 (53)	26,972 (50)	33.4	1.1 (0.8-1.5)
Female (%)	81 (47)	26,572 (50)	30.5	1.0
Age				
18-34 (%)	2 (1)	281 (1)	71.2	5.3 (1.2-22.9)#
35-44 (%)	5 (3)	985 (2)	50.8	3.8 (1.4-10.3)
45-54 (%)	14 (8)	3,235 (6)	43.3	3.2 (1.6-6.6)
55-64 (%)	29 (17)	6,674 (13)	43.5	3.2 (1.7-6.0)
65-74 (%)	55 (32)	13,309 (25)	41.3	3.1 (1.7-5.4)
75-84 (%)	51 (30)	17,969 (34)	28.4	2.1 (1.2-3.7)
85+ (%)	15 (9)	11,091 (21)	13.5	1.0
Median years	70	76		
Race				
White (%)	166 (97)	52,100 (97)	31.9	1.0
Asian (%)	5 (3)	535 (1)	93.5	2.9 (1.2-7.1)+
Other (%)	0	898 (2)	0	0
Unknown	*0*	*11*		

* Unknowns are excluded when calculating percentages.

** Confidence interval.

The ratio is statistically significant according to the chi-square test for trend.

+ The ratio is statistically significant according to the chi-square test.

Characteristics	PAS patients 1998-2003 (N = 171)*	Oregon deaths, same diseases (N = 53,544)*	DWDA deaths per 10,000 Oregon deaths	Rate ratio (95% CI**)
Marital status				
Married (%)	75 (44)	26,003 (49)	28.8	1.0
Widowed (%)	41 (24)	17,742 (33)	23.1	0.8 (0.6-1.2)
Divorced (%)	42 (25)	7,530 (14)	55.8	1.9 (1.3-2.8)+
Never Married (%)	13 (8)	2,168 (4)	60.0	2.1 (1.2-3.7)+
Unknown	*0*	*101*		
Education				
Less than high school (%)	16 (9)	12,954 (25)	12.4	1.0
HS graduate (%)	51 (30)	22,855 (43)	22.3	1.8 (1.0-3.2)
Some college (%)	35 (21)	9,598 (18)	36.5	3.0 (1.6-5.3)
Baccalaureate or higher (%)	69 (40)	7,392 (14)	93.3	7.6 (4.4-13.0)#
Unknown	*0*	*745*		
Residence				
Metro counties (%)	67 (39)	19,333 (36)	34.7	1.0
Coastal counties (%)	14 (8)	4,374 (8)	32.0	0.9 (0.5-1.6)
Other W. counties (%)	79 (46)	22,259 (42)	35.5	1.0 (0.7-1.4)
E. of the Cascades (%)	11 (6)	7,578 (14)	14.5	0.4 (0.2-0.8)+

(*Relevant footnotes are listed on the previous page.*)

Table 3. Underlying illnesses of 171 patients who died during 1998-2003 after ingesting a lethal dose of medication compared with 53,544 Oregonians dying from the same underlying diseases.

Underlying illnesses	PAS patients 1998-2003 (N=171)	Oregon deaths, same diseases (N=53,544)	DWDA deaths per 10,000 Oregon deaths	Rate ratio (95% CI*)
Malignant neoplasms (%)	135 (79)	35,906 (67)	37.6	3.9(2.0-7.6)+
Lung and bronchus (%)	33 (19)	12,037 (23)	27.4	2.8(1.4-5.9)+
Breast (%)	16 (9)	3,037 (6)	52.7	5.4(2.4-12.3)+
Pancreas (%)	16 (9)	2,190 (4)	73.1	7.5(3.3-17.1)+
Colon (%)	10 (6)	3,171 (6)	31.5	3.3(1.3-8.0)+
Prostate (%)	9 (5)	2,670 (5)	33.7	3.5(1.4-8.8)+
Ovary (%)	9 (5)	1,178 (2)	76.4	7.9(3.1-19.9)+
Skin (%)	6 (4)	522 (1)	114.9	11.9(4.2-33.2)+
Other (%)	36 (21)	11,101 (21)	32.4	3.4(1.6-7.0)+
Amyotrophic lateral sclerosis (%)	13 (8)	522 (1)	249.0	25.7(11.1-59.9)+
Chronic lower respiratory dis. (%)	9 (5)	9,300 (17)	9.7	1.0
HIV/AIDS (%)	3 (2)	175 (<1)	171.4	17.7(4.8-64.9)+
Illnesses listed below (%)**	11 (6)	7,641 (14)	14.4	1.5(0.6-3.6)

* Confidence interval.

** Includes aortic stenosis, congestive heart failure, diabetes mellitus with renal complications, gastrointestinal stromal tumor, myelodysplastic syndrome, pulmonary disease with fibrosis, scleroderma, and Shy-Drager syndrome.

+ The ratio is statistically significant according to the chi-square test.

Table 4. Death with Dignity Act participant end of life care and DWDA utilization. Based on physician interviews for 171 patients who died after ingesting a lethal dose of medication - Oregon, 1998-2003.

Characteristics	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
End of Life Care			
Hospice			
Enrolled (%)	39 (93)	106 (83)	145 (86)
Declined by patient (%)	3 (7)	21 (17)	24 (14)
Unknown	–	*2*	*2*
Insurance			
Private (%)	22 (52)	80 (63)	102 (61)
Medicare or Medicaid (%)	20 (48)	44 (35)	64 (38)
None (%)	–	2 (2)	2 (1)
Unknown	–	*3*	*3*
End of Life Concerns+			
Losing autonomy (%)	39 (93)	106 (85)	145 (87)
Less able to engage in activities making life enjoyable (%)	39 (93)	99 (79)	138 (83)
Loss of dignity (%)++	31 (82)	–	31 (82)
Losing control of bodily functions (%)	24 (57)	73 (58)	97 (58)

* Unknowns are excluded when calculating percentages unless otherwise noted.

** Patients discussing concern about inadequate pain control with their physicians were not necessarily experiencing pain.

\+ Affirmative answers only ("Don't know" included in negative answers). Available for 17 patients in 2001.

++ First asked in 2003.

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
End of Life Concerns+ **(Cont'd)**			
Burden on family, friends/ caregivers (%)	16 (38)	44 (35)	60 (36)
Inadequate pain control (%)**	9 (21)	28 (22)	37 (22)
Financial implications of treatment (%)	1 (2)	3 (2)	4 (2)
PAS Process			
Referred for psychiatric evaluation (%)	2 (5)	28 (23)	30 (18)
Patient died at Home (patient, family or friend (%)	39 (93)	121 (94)	160 (94)
Long term care, assisted living or foster care facility (%)	2 (5)	6 (5)	8 (5)
Hospital (%)	0	1 (1)	1 (1)
Other (%)	1 (2)	1 (1)	2 (1)
Lethal Medication			
Secobarbital (%)	4 (10)	85 (66)	89 (52)
Pentobarbital (%)	37 (88)	41 (32)	78 (46)
Secobarbital/ amobarbital (%)	1 (2)	2 (2)	3 (2)
Other (%)	0	1 (1)	1 (1)

(Relevant footnotes are listed on the previous page.)

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Health-care provider present when medication ingested#			
Prescribing physician (%)	12 (29)	22 (39)	34 (34)
Other provider, prescribing physician not present (%)	20 (48)	29 (51)	49 (49)
No provider (%)	10 (24)	6 (11)	16 (16)
Unknown	*0*	*2*	*2*
Regurgitation/seizures after medication ingested			
Regurgitated (%)	3 (7)	4 (3)	7 (4)
Seizures (%)	0	0	0
Neither (%)	39 (93)	121 (97)	160 (96)
Unknown	*0*	*4*	*4*
Emergency Medical Services			
Called for intervention after lethal medication ingested (%)***	0	0	0
Not called after lethal medication ingested (%)	42 (100)	126 (100)	168 (100)
Unknown	*0*	*3*	*3*

* Unknowns are excluded when calculating percentages unless otherwise noted.

*** Excludes calls to pronounce death.

The data shown are for 2001-2003. Information about the presence of a health care provider/volunteer, in absence of the prescribing physician, was first collected in 2001. Attendance by the prescribing physician has been recorded since 1998. During 1998-2002 the prescribing physician was present when 47% of the patients ingested the lethal medication.

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Timing of PAS Event			
Duration (weeks) of patient-physician relationship			
Median	10	13	13
Range	0-405	0-851	0-851
Duration (days) between 1st request and death			
Median	36	43	39
Range	16-737	15-466	15-737
Minutes between ingestion and unconsciousness			
Median	4	5	5
Range	1-20	1-38	1-38
Unknown	*2*	*18*	*20*
Minutes between ingestion death			
Median	20	30	25
Range (minutes - hours)	5m-48h	4m-37h	4m-48h
Unknown	*1*	*12*	*13*

(Relevant footnote is listed on the previous page.)

[LETTERHEAD]

HELLEREHRMAN
ATTORNEYS

Hilary E. Ware
hware@hewm.com
Direct (415) 772-6459
Main (415) 772-6000
Fax (415) 772-6268

March 19, 2003

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Ninth Circuit
P.O. Box 193939
San Francisco, CA 94119-3939

Re: *State of Oregon et al., v. Ashcroft*
Case No. 02-35587

Dear Sir or Madam:

Pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure, the Patient Plaintiffs-Appellees in the above-mentioned case wish to request the Court's permission to cite a significant supplemental authority that has recently been released. On March 6, 2003, the *New England Journal of Medicine* published "Five Years of Legal Physician-Assisted Suicide in Oregon," an examination of data from the fifth year of the Oregon Death With Dignity Act ("ODWDA"). The Patient Plaintiffs-Appellees cited and discussed the data contained in the reports from the first four years of the ODWDA in their Brief at pages 13-14; the report from the fifth year should also be considered in that context.

A copy of this report is enclosed with this request, and is also available at www.http://content.nejm.org/cgi/content/full/348/10/961. Thank you for your consideration of this request.

Very truly yours,

/s/ HILARY E. WARE
Hilary E. Ware

cc: All Counsel of Record
Enclosures

[Letterhead bottom:]

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Volume 348:961-964
March 6, 2003
Number 10

Five Years of Legal Physician-Assisted Suicide in Oregon

To the Editor: Physician-assisted suicide for terminally ill residents of Oregon has been legal since October 1997.[1] Although it has been challenged several times in court and by a referendum, the Oregon Death with Dignity Act remains in effect at this time. As the state public health agency with the mandate to monitor the use of physician-assisted suicide, we require physicians to file reports on patients for whom a prescription for a lethal medication is written. We analyzed data from these report forms, interviews with physicians, and death certificates. As part of follow-up to previous reports,[2,3,4,5] we characterized patients who died in 2002 after ingesting legally prescribed lethal medications and evaluated trends in the numbers of prescriptions written and in the numbers and characteristics of the patients who ingested lethal medications during the five years since implementation. We compared all patients who chose physician-assisted suicide during the first five years with other residents of Oregon who died of the same underlying diseases.

During 2002, 33 physicians wrote prescriptions for lethal medications for 58 Oregon residents. The number of prescriptions written has increased over the five-year period since implementation (24 in 1998, 33 in 1999, 39 in 2000, 44 in 2001, and 58 in 2002; P for trend <0.001 by the chi-square test). During 2002, 38 persons died from ingesting the prescribed lethal medications, and 8 who received prescriptions for lethal medications are still alive (6 of them received prescriptions in 2002, and 2 of them received prescriptions in 2001). The number of patients who died from ingesting prescribed lethal medications has increased since 1998 (16 in 1998, 27 in 1999, 27 in 2000, 21 in 2001, and 38 in 2002; P for trend <0.02 by the chi-square test).

In the five years during which the law has been in effect, a total of 129 people used physician-assisted suicide in Oregon. This corresponds to a rate of 8.8 per 10,000 deaths from any cause in Oregon. *Table 1* shows the characteristics of patients who have ingested prescribed lethal medications since legalization. Among Oregon residents who died of the same underlying diseases as those who chose physician-assisted suicide, rates of use of physician-assisted suicide decreased with age and were higher among those who had been divorced and among those with higher levels of educational attainment. The rate of use of physician-assisted suicide was significantly higher among those who had amyotrophic lateral sclerosis (374.5 per 10,000) or cancer (61.0 per 10,000) than among those who had other terminal illnesses. Men and women were equally likely to choose physician-assisted suicide. Although the majority of patients were non-Hispanic whites, the rate of use of physician-assisted suicide among terminally ill Asian Americans was higher (91.7 per 10,000) (*Table 1*).

Despite increases, the number of terminally ill Oregon residents using physician-assisted suicide remains small relative to the overall number of deaths.

Katrina Hedberg, M.D., M.P.H.
David Hopkins, M.S.
Melvin Kohn, M.D., M.P.H.
Oregon Public Health Services
Portland, OR 97232
katrina.hedberg@state.or.us

References

1. Oregon's Death with Dignity Act. Oregon revised statute 127.800-127.995. Portland: Oregon Public Health Services, 2003. (Accessed February 14, 2003, at http://www.healthoregon.org/chs/pas/pas.cfm.)
2. Chin AE, Hedberg K, Higginson GK, Fleming DW. Legalized physician-assisted suicide in Oregon--the first year's experience. N Engl J Med 1999;340:577-583. [Abstract/Full Text]
3. Sullivan AD, Hedberg K, Fleming DW. Legalized physician-assisted suicide in Oregon--the second year. N Engl J Med 2000;342:598-604. [Abstract/Full Text]
4. Sullivan AD, Hedberg K, Hopkins D. Legalized physician-assisted suicide in Oregon, 1998-2000. N Engl J Med 2001;344:605-607. [Full Text]
5. Hedberg K, Hopkins D, Southwick K. Legalized physician-assisted suicide in Oregon, 2001. N Engl J Med 2002;346:450-452. [Full Text]

Table 1. Characteristics of Patients in Oregon Who Died after Ingesting Legally Prescribed Lethal Medication and of All Patients Who Died from the Same Underlying Diseases.

June 5, 1998

The Honorable Henry J. Hyde
Chairman
Committee on the Judiciary
U.S. House of Representative
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request concerning the question whether the Department of Justice, through the Drug Enforcement Administration ("DEA"), may invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971, to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act," Oreg. Rev. Stat. §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

The Oregon Act was approved by Oregon voters on November 8, 1994, and went in to effect on October 27, 1997. The Act provides for a detailed procedure by which a mentally competent, terminally ill patient may request to end his or her life "in a humane and dignified manner." O.R.S. § 127.805. The procedure requires, for example, that the patient's competence and the voluntariness of the request be documented in writing and confirmed by two

witnesses, *see id.* § 127.810(1), that the patient's illness and competence and the voluntariness of the request by [*sic*] confirmed by a second physician, *see id.* § 127.820, and that the physician and patient observe certain waiting periods, *see id.* §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient's attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

Prior to the Oregon Act's taking effect last year, you wrote to DEA Administrator Thomas Constantine seeking the DEA's view as to whether delivering, distributing, dispensing, prescribing, or administering a controlled substance with the intent of assisting in a suicide would violate the CSA notwithstanding a state law such as the Oregon Act. In response, Administrator Constantine explained that "physician-assisted suicide would be a new and different application of the CSA," and that the determination whether to pursue adverse action under the CSA would first require "a medico-legal investigation" involving "state and local law enforcement agencies and prosecutors." He also stated, however, that "the activities that you described in your letter to us would be, in our opinion, a violation of the CSA." Subsequently, many other Members of Congress have sent letters urging that I support the DEA's conclusions and enforce federal laws and regulations accordingly. I have received other correspondence supporting a contrary conclusion.

The Department has conducted a thorough and careful review of the issue of whether the CSA authorizes adverse

action against a physician who prescribes a controlled substance to assist in a suicide in compliance with Oregon law.

The CSA is a complex regulatory scheme that controls the authorized distribution of scheduled drugs. Physicians, for example, are authorized to prescribe and distribute scheduled drugs only pursuant to their registration with the DEA, and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The relevant provisions of the CSA provide criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. 802 (21), *see id.* § 841 (b), and provide for revocation of the DEA drug registrations of physicians who have engaged either in such criminal conduct or in other "conduct which may threaten the public health and safety," *id.* § 823 (f). Because these terms are not further defined by the statute, we must look to the purpose of the CSA to understand their scope.

The CSA was intended to keep legally available controlled substances within lawful channels of distribution and use. *See* S. Rep. No. 91-613, at 3 (1969). It sought to prevent both the trafficking in these substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress intended to prevent was that deriving from the drug's "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811 (f).

There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regu-

lating the practice of medicine that involves legally available drugs (except for certain specific regulations dealing with the treatment of addicts, see 42 U.S.C. § 257a; 21 C.F.R. § 291.505).

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," *Washington v. Glucksberg*, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances. If Congress had assigned DEA this role under the CSA, it would ultimately be DEA's task to determine whether assistance in the commission of a suicide, in compliance with a state law specifically permitting and regulating suck [*sic*] assistance, nevertheless falls outside the public interest. These questions, however, are not susceptible of scientific or factual resolution, but rather are fundamental questions of morality and public policy. Such a mission falls well beyond the purpose of the CSA.

The state of Oregon has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we have concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law. We emphasize that out [*sic*] conclusion is limited to these particular circumstances. Adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the federal government's pursuit of adverse

actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA.

Finally, notwithstanding our interpretation of the CSA as it applies to the Oregon Act, it is important to underscore that the President continues to maintain his longstanding position against assisted suicide and any Federal support for that procedure. This position was recently codified when he signed the Assisted Suicide Funding Restriction Act last year. While states ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex but extremely important issue.

Sincerely,

Janet Reno

[LETTERHEAD]

[Round Seal]

DEPARTMENT OF JUSTICE

1162 Court Street NE
Justice Building
Salem, Oregon 97301-4096

Telephone (503) 378-4400
TTY: (503) 378-5938

February 2, 2001

Honorable John Ashcroft
Attorney General of the United States
United States Department of Justice
Room 5111
Tenth and Constitution Avenues, NW
Washington, DC 20530

Dear Attorney General Ashcroft:

I want to extend warmest congratulations on your confirmation and accession to office as Attorney General of the United States. Given your former service as Attorney General of Missouri and your active role in the National Association of Attorneys General, I know you assume your new office with a strong understanding of the many-faceted relationship between state and territorial Attorneys General and the United States Department of Justice. I look forward to joining my counterparts in the other states and territories in making that relationship with your administration as cordial and productive as possible.

In your new service you may soon be addressing an issue of major significance to my state: whether to support a reversal of the United States Department of Justice's present interpretation of the Federal Controlled Substances Act (CSA) in relation to physician prescription of controlled substances in circumstances that comply with Oregon's physician-assisted suicide law (Ballot Measure 16). As you may know, the people of Oregon adopted that law by initiative and later rejected a measure, referred to them by the Oregon Legislative Assembly, repealing Ballot Measure 16.

In 1997 the United States Department of Justice concluded that the CSA does not authorize the Drug Enforcement Administration to revoke a physician's federal controlled substances registration on the ground the physician has prescribed controlled substances in conformity with Ballot Measure 16. That conclusion followed a meeting with the Department of Justice at which my representative, joined by a representative of Governor Kitzhaber, had the opportunity to present our legal analysis supporting the interpretation of the CSA the Department of Justice later adopted.

Some have speculated that the previous interpretation of the CSA may be reexamined and possibly reversed. Such reversal would presumably subject Oregon physicians to DEA revocation of their controlled substances registration, and possible criminal prosecution, if they prescribe controlled substances in compliance with Ballot Measure 16.

If the current interpretation of the CSA in relation to Ballot Measure 16 is to be reexamined, Governor Kitzhaber and I request a renewed opportunity for our representatives to meet with yours to discuss my office's

analysis of the CSA in relation to Ballot Measure 16. We make that request, of course, from a desire to avoid a CSA interpretation we believe would be inconsistent with Congress' intent in enacting the CSA, and a resulting course of CSA enforcement we believe would therefore be unlawful.

Again, please accept sincerest congratulations on your assuming an office of great importance in the life of our nation.

Respectfully yours,

/s/ HARDY MYERS
HARDY MYERS
Attorney General

cc: Governor John Kitzhaber
United States Senator Ron Wyden
United States Senator Gordon Smith

[LETTERHEAD]

[Round Seal] U.S. Department of Justice
Office of Intergovernmental Affairs

Office of the Director *Washington, D.C. 20530*
April 17, 2001

The Honorable Hardy Myers
Attorney General
State of Oregon
Salem, OR 97301-4096

Dear Attorney General Hardy:

Thank you for your letter of February 2, 2001, to the Attorney General congratulating him on his confirmation. I am sorry for the delay in responding. In your letter you expressed concern that the Department may revisit its existing interpretation of the Controlled Substances Act (CSA) as it applies to physicians prescribing a controlled substance to assist in a suicide. The Attorney General has asked me to respond on his behalf.

I am aware of no pending legislation in Congress that would prompt a review of the Department's interpretation of the CSA as it relates to physician-assisted suicide. Should such a review be commenced in the future, we would be happy to include your views in that review.

On behalf of the Attorney General, I thank you for writing and expressing your views on this important matter.

Sincerely,

/s/ LORI SHARPE
Lori Sharpe
Director and Advisor
to the Attorney General

(5)

Supreme Court, U.S.
FILED
JAN 7 - 2005
OFFICE OF THE CLERK

No. 04-623

IN THE
SUPREME COURT OF THE UNITED STATES

John Ashcroft, Attorney General, *et al.*,

Petitioners,

v.

State of Oregon *et al.*,

Respondents.

On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

RESPONDENTS' BRIEF IN OPPOSITION
filed by Peter A. Rasmussen, M.D.
and David M. Hochhalter, RPh

ELI D. STUTSMAN
Counsel of Record
621 SW Morrison
Thirteenth Floor
Portland, OR 97205
(503) 274-4048

January 10, 2005

QUESTION PRESENTED

Exercising its traditional police powers, Oregon enacted laws and regulations that allow physicians to prescribe and pharmacists to dispense Schedule II controlled substances to competent, terminally-ill adults who may use them under strictly regulated conditions to choose the time, place, and manner of their impending deaths. In enacting and amending the Controlled Substances Act (CSA), did Congress clearly authorize the Attorney General to determine that physicians and pharmacists acting in accordance with those Oregon laws have violated the CSA?

TABLE OF CONTENTS

Page No.

Question Presented i
Table of Contents ii
Table of Authorities iii
Table to Appendix v
Introduction 1
Statement of the Case 1
Proceedings below 1
The Attorney General's enforcement directive 3
The Oregon Death With Dignity Act 6
Reasons to Deny the Writ 7
1. The Attorney General exceeds the role of his office and the scope of the CSA 7
2. The Attorney General misconstrues this Court's precedent 7
3. The Attorney General fails to allow the integration of state and federal law 9
4. The Attorney General misuses the regulatory phrase "legitimate medical purpose" 13
5. The regulation of medicine belongs to the States . . . 15
6. The practice of medicine in Oregon 17
7. The CSA is a law enforcement statute, not a medical policy act 19
8. The Attorney General fails to allege a single incident of illicit drug use, drug trafficking, or drug diversion 27
Conclusion 28

TABLE OF AUTHORITIES

cases — Page No.

Alden v. Maine,
527 U.S. 706 (1999) 16

Barsky v. Board of Regents,
347 U.S. 442 (1953) 15, 16, 18

Gregory v. Ashcroft,
501 U.S. 452, 458 (1991) 16

Linder v. United States,
268 U.S. 5 (1924) 15, 16, 18

Printz v. United States,
521 U.S. 898 (1997) 16

Raygor v. Regents of University of Minnesota,
534 U.S. 533 (2002) 28

Rush Prudential HMO, Inc. v. Moran,
536 U.S. 355 (2002) 16, 18

United States v. Green,
511 F.2d 1062 (1975) 20

United States v. Moore,
423 U.S. 122 (1975) 11, 12, 14

Page No.

cases

United States v. Oakland Cannabis Buyer's Cooperative, 532 U.S. 483 (2001) 8

Washington v. Glucksberg, 521 U.S. 702 (1997) 6, 28

statutes

21 U.S.C. 801 19

21 U.S.C. 802(21) 11

21 U.S.C. 822(a)(2) 10

21 U.S.C. 822(b) 11

21 U.S.C. 829 14

21 U.S.C. 829(a)&(b) 11

21 U.S.C. 829(c) 14

21 U.S.C. 841(a)(1) 10

21 U.S.C. 903 . . . . . 9, 17

Or. Rev. Stat. 127.800 *et seq.* 1, 19

Page No.

statutes

Or. Rev. Stat. 127.815 . . . . . 18, 19

Or. Rev. Stat. 127.815(1)(l)(A) 17

Or. Rev. Stat. 127.855(1)(1)(7) 5

Or. Rev. Stat. 127.865(3) 5

Or. Rev. Stat. 163.125(1)(b) 6

rules

21 C.F.R. 1306.04(a) 4, 14

APPENDIX

The Oregon Death With Dignity Act 1

The Oregon Assisted Suicide Statute 21

Affidavit of Peter A. Rasmussen, M.D. 22

Affidavit of David M. Hochhalter, RPh 28

Affidavit of David M. Hochhalter, RPh 31

INTRODUCTION

One day after the State of Oregon filed suit, respondents Peter A. Rasmussen, M.D., and David M. Hochhalter, Rph, both of whom are registered with the Drug Enforcement Administration (DEA), filed a complaint in intervention suing United States Attorney General John Ashcroft, *et al.*, to prevent criminal and civil enforcement proceedings against them for having prescribed and dispensed controlled substances under the Oregon Death With Dignity Act, Or. Rev. Stat. 127.800 *et seq.*

STATEMENT OF THE CASE

A. *Proceedings below*

On November 8, 2001, the district court granted respondents' request for a temporary restraining order, enjoining the Attorney General from enforcing the CSA against Oregon physicians and pharmacists practicing in accord with the Oregon Death With Dignity Act. CR 20.

On November 20, 2001, at the conclusion of the preliminary injunction hearing, the parties agreed to extend the TRO in lieu of a court ruling on plaintiffs' motion for a preliminary injunction. CR 60.

On April 17, 2002, the district court granted summary judgment in favor of all plaintiffs, enjoining the Attorney General from enforcing, applying, or otherwise giving any legal effect to his enforcement directive. *See*, Pet. Cert., 97a. The district court reasoned as follows:

> I conclude that Congress did not intend the CSA to override a state's decisions concerning what constitutes legitimate medical practice, at least in the absence of an express federal law prohibiting that practice. Similarly, I conclude that Congress never intended, through the CSA or through any other current federal law, to grant blanket authority to the Attorney General or the DEA to define, as a matter of federal policy, what constitutes the legitimate practice of medicine.

Pet. Cert., 97a.

On May 26, 2004, the Ninth Circuit affirmed the district court's analysis, finding that the enforcement directive is unlawful and unenforceable because it:

> [1] violates the plain language of the CSA, [2] contravenes Congress' express legislative intent, and [3] oversteps the bounds of the Attorney General's statutory authority.

Pet. Cert., 2a; *see, also, id.* at 9a:

> We hold that the Attorney General lacked Congress' requisite authorization. The Ashcroft Directive violates the "clear statement" rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

The Ninth Circuit concluded its analysis as follows:

> In sum, the CSA was enacted to combat drug abuse. To the extent that it authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of Health and Human Services, not to the Attorney General. The Attorney General's unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds the scope of his authority under federal law. We therefore hold that the Ashcroft Directive is invalid and may not be enforced.

Id. at 24a.

The Attorney General now petitions this Court for review.

B. *The Attorney General's enforcement directive*

In a two page enforcement directive (Pet. Cert. 100a-1005a) released November 6, 2001, the Attorney General found as follows:

> 1. *Determination on Use of Federally Controlled Substances to Assist Suicide.* For the reasons set forth in the OLC Opinion, *I hereby determine that assisting suicide is not a "legitimate medical purpose"* within the meaning of 21 CFR § 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA. Such conduct by a physician registered to dispense controlled substances may "render his registration * * * inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). This conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted.

See, Pet. Cert., 1002a (emphasis added).

The Attorney General directed that his findings be immediately enforced:

> I hereby direct the DEA, *effective upon publication of this memorandum in the Federal Register*, to enforce and apply this determination, notwithstanding anything to the contrary in the June 5, 1998, Attorney General [Janet Reno]'s letter.

See, Pet. Cert., 102a-103a (emphasis added). The enforcement directive went into effect three days later upon being published in the Federal Register on November 9, 2001. *Id.* at 100a.

The Attorney General further dictated the enforcement strategy. The Oregon Death With Dignity Act[1] imposes statutory record keeping requirements upon physicians[2] and public reporting requirements upon the Oregon Department of Human Services.[3] The Attorney General concluded that those publicly held records would facilitate enforcement proceedings:

> 4. Enforcement in Oregon. * * * . Those records should contain the information necessary to determine whether those holding DEA registrations who assist suicides *in accordance with Oregon law* are prescribing federally controlled substances for that purpose in violation of the CSA * * * .

See, Pet. Cert., 103a-104a (emphasis added).

---

[1] In his petition, the Attorney General appends only portions of the Oregon statute. The full text of the statute is appended here at App. 1-20.

[2] *See*, App. 9-10, Or. Rev. Stat. 127.855(1)-(7) (medical record documentation requirements).

[3] *See*, App. 11, Or. Rev. Stat. 127.865(3) (reporting requirements).

The Attorney General determined that the DEA had the authority to obtain those records, *id.* at 104a, and concluded his enforcement directive with a distribution instruction:

> 5. Distribution. Please ensure that this Memorandum and the OLC opinion on which it is based are promptly distributed to appropriate DEA personnel, *especially those with authority over the CSA in Oregon.*

Id. (emphasis added).

C. *The Oregon Death With Dignity Act*

In *Washington v. Glucksberg*, 521 U.S. 702 (1997), this Court declined to recognize a "generalized" constitutional right to a physician-assisted death.[4] Central to that result was the court's observation that, "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Id.* at 719. "Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735. The issue is one that "is entrusted to the 'laboratory' of the States." *Id.* at 737 (O'Connor, J., concurring, joined by Justices Ginsberg and Breyer); *see, also, id.* at 738 (Stevens, J., concurring) and at 788 (Souter, J., concurring).

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[4] Respondents use the term "assisted death" in recognition of the fact that "assisted suicide" is still a crime in Oregon. *See,* App. 21, Or. Rev. Stat. 163.125(1)(b). It is preferable not to use the language of a crime when referring to non-criminal activity under Oregon law.

Oregon has been at the forefront of this debate. The Oregon Death With Dignity Act was adopted by the people of Oregon at the November 8, 1994 election. Three years later, on November 7, 1997, the people of Oregon decisively rejected, by a margin of 60 percent to 40 percent, a proposal to repeal the Oregon Death With Dignity Act. Two years after that, on June 30, 1999, Governor John Kitzhaber, M.D., signed into law Senate Bill 491, amending the Oregon Death With Dignity Act. *See, e.g.*, CR 103, 106. In sum, the Oregon Death With Dignity Act is a duly enacted state law, twice approved by Oregon voters, subsequently amended by the state legislature and signed into law by Oregon's governor, himself a medical doctor. It is a rare law that has been so thoroughly tested and approved by a state's democratic process.

REASONS TO DENY THE WRIT

1. *The Attorney General exceeds the role of his office and the scope of the CSA*

As both the district court and the Ninth Circuit held, quoted *supra*, the Attorney General, in issuing his enforcement directive, exceeds the role of his office and the bounds of the CSA as he enters this policy dispute with the State of Oregon. The district and circuit courts have squarely addressed this problem and respondents urge this Court to end this litigation now.

2. *The Attorney General misconstrues this Court's precedent*

The Attorney General's November 6, 2001 enforcement directive is premised upon a misapplication of this Court's May

14, 2001 decision in *United States v. Oakland Cannabis Buyer's Cooperative*, as follows:

> As you are aware, the Supreme Court reaffirmed last term that the application of federal law regulating controlled substances is uniform throughout the United States and may not be nullified by the legislative decisions of individual States. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001).

Pet. Cert., 101a. Unlike the "medical marijuana" litigation emerging from California, however, the Oregon law (1) does not authorize or require the use of Schedule I banned drugs, (2) no one is asserting a "medical necessity" defense, and (3) Oregon has not sought to legalize what the CSA has banned. In sharp contrast to the California cases, the Oregon law requires only drugs that are lawfully prescribed in all 50 states,[5] and Oregon does not challenge the CSA's classification scheme. The Attorney General does not claim otherwise, and his steadfast reliance upon *Oakland Cannabis Buyers' Coop.*[6] is therefore misplaced.

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[5] The Attorney General concedes this point too. *See*, Pet. Cert., 17, fn 4; *see, also*, Affidavit of Peter A. Rasmussen, M.D., App. 22 ¶ 4 and App. 26 ¶ 17; Affidavit of David M. Hochhalter, RPh, App. 29 ¶ 5 and App. 31 ¶ 4.

[6] *See, e.g.*, Pet. Cert., 6, 10, 15, 16, 17, 20, 22, 26.

3. *The Attorney General fails to allow the integration of state and federal law*

There is no positive conflict between state and federal law such that the two "cannot consistently stand together." 21 U.S.C. 903 (Application of State law).[7] The Attorney General may enforce the "uniform national policy" intended by Congress to prevent illicit drug use, drug trafficking, and drug diversion and, contemporaneously, Oregon practitioners, registered with the Board of Medical Examiners and the DEA, may possess, prescribe, and/or dispense controlled substances within "the course of their professional practice." These two policies are not mutually exclusive.

The CSA describes unlawful conduct as follows:

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[7] Section 903 (Application of State law) provides:

> No provision of this title shall be construed as indicating an intent on the part of the Congress *to occupy the field in which that provision operates*, including criminal penalties, to the exclusion of any State law on the same subject matter *which would otherwise be within the authority of the State*, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.

21 U.S.C. 903 (emphasis added).

(a) Unlawful acts

Except as authorized by this subchapter, *it shall be unlawful for any person knowingly or intentionally--*

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; * * * .

21 U.S.C. 841(a)(1) (emphasis added). Thus, it is a crime to (1) knowingly or intentionally (2) distribute or dispense a controlled substance, unless "authorized" by the Act. *Id.* Authorization is obtained by "registering" with the Attorney General:

> (2) Every person who dispenses, or who proposes to dispense, any controlled substance, *shall obtain from the Attorney General a registration* issued in accordance with the rules and regulations promulgated by him. * * * .

21 U.S.C. 822(a)(2) (emphasis added). Persons registered with the Attorney General are authorized to possess, manufacture, distribute, or dispense controlled substances to the extent authorized by their registration:

> **(b) Authorized activities.**
>
> Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances * * * are authorized to possess, manufacture, distribute, or dispense such substances or chemicals * * * *to the extent*

> *authorized by their registration and in conformity with the other provisions of this title.*

21 U.S.C. 822(b) (emphasis added). A physician registered with the Attorney General is a "practitioner" authorized to dispense controlled substances, *see*, 21 U.S.C. § 829(a)&(b), in "the course of professional practice," as follows:

> (21) The term "practitioner" means a *physician*, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, *registered, or otherwise permitted, by the United States or the jurisdiction in which he practices* or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance *in the course of professional practice* or research.

21 U.S.C. 802(21), formerly 802(20), (emphasis added).

This Court, in *United States v. Moore*, 423 U.S. 122 (1975), clarified that the course of professional practice standard is the applicable standard under the CSA:

> * * * the CSA uses the concept of "registration." Section 822(b) defines the scope of authorization under the Act in circular terms: "Persons registered under

> this subchapter are authorized to dispense controlled substances to the extent authorized by their registration and in conformity with the other provisions of this subchapter." *But the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice."*

Moore, 423 U.S. 122, 140 (emphasis added, internal ellipses, brackets and footnotes omitted). Under this statutory scheme, the Attorney General may enforce the uniform national policy intended by Congress to prevent illicit drug use, drug trafficking, and drug diversion, and Oregon practitioners may possess, prescribe, and dispense controlled substances in the "course of their professional practice." The Attorney General simply erred when he applied his own subjective standard:

> Nothing in either the CSA or its implementing legislation makes the definition of *legitimate medical purpose* dependent upon state law.

Pet. Cert., 19 (emphasis added).

4. *The Attorney General misuses the regulatory phrase "legitimate medical purpose"*

The regulatory phrase "legitimate medical purpose," upon which the Attorney General so heavily relies,[8] is not the value laden term the Attorney General portrays it to be. This phrase is not found in the CSA but is instead rooted in an agency rule and is therefore limited by the statutory phrase from which it is derived, "the course of professional practice," and it means the same thing. The Attorney General attempts to change the plain meaning of this statutory language by infusing into it new meaning derived from an agency rule:

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[8] *See, e.g.*, Pet. Cert., 9 ("the dissent observed that the Attorney General's conclusion that physician-assisted suicide is not a legitimate medical purpose is well supported by an 'overwhelming historical, legal, and medical consensus'"), 12 ("The Attorney General clearly acted reasonably in concluding that dispensing drugs to assist a person to commit suicide is not for a 'legitimate medical purpose' within the meaning of the CSA and his implementing regulation"), 12 ("numerous health care experts have agreed that physician-assisted suicide is not a legitimate medical treatment"), 13-14 ("The federal regulatory scheme is built upon the dual principles that the dispensing of controlled substances should be allowed for such 'legitimate medical purposes" but that distribution for illegitimate purposes should be prohibited"), 14 ("legitimate 'medical use' in 'treatment' therefore is a prerequisite to such dispensing"), 24 ("the determination whether dispensing drugs to facilitate suicide constitutes a 'legitimate medical purpose' turns on an interpretation of the CSA and a regulation of the Attorney General, and does not require an assessment of medical or scientific evidence").

> As this Court indicated in *Moore*, this *legitimate medical purpose* requirement is implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See, *Moore* 423 U.S. at 137-139 & n.13.

Pet. Cert. 4 (emphasis added). Correctly stated, this Court said:

> The only limitation on the distribution or dispensing of Schedule V drugs is that it be "for a *medical purpose*." s 829(c). The *medical purpose requirement* explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation s 306.04 makes it explicit.

Moore, 423 U.S. at 137 n.13 (emphasis added). The Attorney General has thus transformed "medical purpose," a phrase consistent with the statutory "course of professional practice" standard, into the value laden term that he prefers, "legitimate medical purpose." This Court in *Moore* never went so far and a simple word search indicates that the phrase "legitimate medical purpose" was used only one time, in footnote 12, when the Court quoted the text of 21 CFR § 1306.04(a). 423 U.S. at 136-137 n.12. Elsewhere in his petition, the Attorney General concedes, as he must, that departure from the "course of professional practice" is the true standard from *Moore*:

> This Court held that the CSA was intended to limit a physician's distribution

> of controlled substances to actions "as a physician" and in the course of "professional practice." 423 U.S. at 140, 141.

Pet. Cert. 18. Nonetheless, the Attorney General repeatedly uses the language from the rule to the exclusion of the language from the statute as a rhetorical device to shift the debate to one about the legitimacy of medicine. For example, the Attorney General writes that he has "canvassed" the views of the medical community, state and federal law, and judicial opinions, and:

> despite Oregon voters' approval, physicians assisted suicide is not a "*legitimate medical purpose*."

Pet. Cert., 6 (emphasis added). Correctly stated, however, the question is whether the controlled substances at issue in Oregon are being prescribed or dispensed "in the course of professional practice," not whether a state's determination to allow a hastened death for a terminally ill, competent, adult patient is "legitimate" in the opinion of the Attorney General.

5. *The regulation of medicine belongs to the States*

The states, not the federal government, regulate medicine. *See, e.g., Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the states is beyond the power of the federal government."); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1953)("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a

vital part of a state's police power."); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (determination of medical necessity and standards of reasonable care are "quintessentially state-law" determinations). Although the Attorney General criticizes *Linder*, *supra*, as an outdated *Lochner*-era opinion (Pet. Cert., 22, 27), similar propositions are found in *Barsky* and *Rush Prudential HMO*, *supra*.

The framers of the Constitution "split the atom of sovereignty" two ways: horizontally (among the three branches of government) and vertically (between the federal and state governments). *See, Alden v. Maine*, 527 U.S. 706, 714-15, 751 (1999); *Printz v. United States*, 521 U.S. 898, 921-22 (1997). As this Court recently explained:

> This separation of the two spheres is one of the Constitution's structural protections of liberty. "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, *a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.*"

Printz, 521 U.S. at 921 (emphasis added); *quoting, Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

The Congress, when legislating and later amending the CSA, was certainly aware of the traditional and constitutional

allocation of power that resides at the core of our federal form of government, and it expressly provided that, "absent a positive conflict," the CSA does not prohibit the states from legislating on, "subject matter which would otherwise be within the authority of the State." 21 U.S.C. 903 (Application of State law). Although the Attorney General concedes in his enforcement directive (Pet. Cert., 100a-105a) and supporting memorandum (*id.* at 106a-148a) that Oregon physicians and pharmacists are practicing medicine in accordance with Oregon law,[9] he offers only tortured arguments to justify his intrusion, a problem that has already been corrected by the district and circuit courts.

6. *The practice of medicine in Oregon*

Unlike the Attorney General, the State of Oregon recognizes the limits and integration of state and federal law. Or. Rev. Stat. 127.815(1)(I)(A) expressly requires physicians and pharmacists practicing under Oregon's unique law to be registered with the Board of Medical Examiners *and* the DEA.[10]

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[9] *See, e.g.*, Pet. Cert., 100a ("regardless of whether state law authorizes or permits such conduct"); 102a ("This conclusion applies regardless of whether state law authorizes or permits such conduct"); 104a ("assist suicides in accordance with Oregon law"); 104a ("in compliance with Oregon Law"); 107a ("even in a manner permitted by state law"); 116a ("legalized physician-assisted suicide"); 131a ("assisting in suicide may be permitted in some cases for Oregon physicians under local law"); 131a ("in accordance with state law"); 133a ("permissible under state law"); 134a ("physicians may assist suicides compatibly with local law"); 148a ("state that had legalized physician-assisted suicide").

[10] *See*, App. 7 (Or. Rev. Stat. 127.815(1)(I)(A)).

As part of his record in support of injunctive relief, Dr. Rasmussen demonstrated that he and others like him practicing under Oregon's unique law are acting in their professional role in conformity with state medical practice standards (App. 22-27), an area that falls squarely within the states' traditional police power. *Linder*, *supra*, 268 U.S. at 18; *Barsky*, *supra* 347 U.S. at 449; *Rush Prudential HMO*, *supra*, 536 U.S at 387.

Or. Rev. Stat. 127.815 establishes the standard of care for an attending physician practicing under the Oregon Death With Dignity Act. App. 4-5.[11] Dr. Rasmussen is acting in the course of his professional practice when he is acting in accord with Oregon's standard of care. He makes an initial determination of whether his patient has a terminal disease, is capable, and has made the request voluntarily. He ensures that the patient is making an informed decision by informing the patient of the patient's medical diagnosis, prognosis, the potential risk and probable result associated with taking the medication to be prescribed, and the feasible alternatives, including, but not limited to, comfort care, hospice care and pain control. Dr. Rasmussen further refers his patients to a consulting physician for medical confirmation of the diagnosis and for a second opinion that the patient is capable and acting voluntarily. When appropriate, Dr. Rasmussen also refers his patients for counseling. He recommends that the patient notify next of kin and counsels the patient about the importance of having another person present when the patient takes

[11] Respondents do not seek to convince this Court that the State of Oregon has made a *correct* policy choice, only that the State of Oregon has made *a* policy choice, implementing a matter of medical policy traditionally reserved to the states.

the medication prescribed under Oregon law. CR 105; App. 24-25, ¶¶ 10, 11.

As required under Oregon law, Dr. Rasmussen dispenses the medications directly, including ancillary medications intended to facilitate the desired effect and minimize the patient's discomfort, or in the alternative, Dr. Rasmussen contacts a pharmacist and informs the pharmacist of the prescription, and he then delivers the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician, or the patient's chosen agent. CR 105; App. 25 ¶ 12.

Dr. Rasmussen further satisfies all of the statutory medical documentation requirements and provides a copy of his dispensing record to the Department of Human Services. In sum, Dr. Rasmussen ensures that all appropriate steps are carried out in accordance with Or. Rev. Stat. 127.800 to 127.897, CR 105; App. 25, ¶ 13, exactly what is required of him under state statutory and regulatory law, and the community standard of care. *See, e.g.*, Or. Rev. Stat. 127.815; App. 1-12.

7. *The CSA is a law enforcement statute, not a medical policy act*

Section 101 of the CSA (21 U.S.C. 801) expresses Congressional concern over the "illegal importation, manufacture, distribution, and possession and improper use of controlled substances," and explains why intrastate trafficking in controlled substances must be regulated in order to address the larger drug abuse problem. These legislative findings, along with the text and legislative history, confirm that the CSA was enacted to control

trafficking in illegal drugs, such as heroin and marijuana, and also to prevent diversion of legitimately produced controlled substances into illicit channels. *See, e.g., United States v. Green*, 511 F.2d 1062, 1071 (1975) (pharmacist dispensed over a million Ritalin tablets in less than a year); HR Rep No. 91-1444, 91st Cong, 2d Sess, U.S.C.C.A.N. 4566, 4581 (1970) (in 1965, almost half of the 9 billion amphetamines and barbiturates produced legitimately in this country were diverted into illicit channels). The goal is to establish "a 'closed' system of drug distribution for legitimate handlers of such drugs" to "reduce the widespread diversion of these drugs out of legitimate channels into the illicit market." 91 U.S.C.C.A.N. at 4571-72; *see, also,* S Rep No 98-225, 98th Cong, 1st Sess, U.S.C.C.A.N. 3182, 3442-49 (1983).

The legislative record further demonstrates that the CSA is a law enforcement statute and that Congress never intended that it would be used to regulate medicine or to alter the state/federal framework.

The following excerpts from the 1970 Senate floor debate reveal that the CSA was at first focused solely upon preventing drug trafficking and diversion; it served a law enforcement purpose and no other purpose:

> This measure--in concept, in spirit, and in detail--*is a law-enforcement measure*. It only approaches one side of the problem of drug abuse.

Quoting, Senator Hughes, Cong. Rec., Senate, 973 (January 23, 1970) (emphasis added).

> That is my position on this problem. The legislation before us is a *law enforcement bill*. * * * we concluded it would be better to keep this particular piece of legislation *a law enforcement measure*.

Quoting, Senator Dodd, Cong. Rec., Senate, 976 (January 23, 1970) (emphasis added).

> The proposed legislation provides a regulatory schedule for the lawful manufacture, distribution, and dispensing of controlled drugs to furnish us with better law enforcement tools *so that the rampant drug abuse problem can finally be curbed* effectively.

Quoting, Senator Dodd, Cong. Rec., Senate, 978 (January 23, 1970) (emphasis added).

> But it cannot be overemphasized that the bill before the Senate today is *entirely concerned with enforcement*. It contains no medical or rehabilitative provisions.
>
> It is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls. * * * .

Quoting, Senator Dodd, Cong. Rec., Senate, 978 (January 23, 1970) (emphasis added).

> * * * this title reaffirms the Federal Government's role in drug control. Basically this role is to regulate the legitimate drug trade *to prevent diversion of medically useful dangerous drugs* into illegitimate channels and *to help reduce the criminal traffic* in all narcotic and dangerous drugs on the local, national, and international level.

Quoting, Senator Dodd, Cong. Rec., Senate, 996 (January 24, 1970) (emphasis added).

> *All of these provisions are designed to reduce the diversion of drugs* from the legitimate course of commerce and use into illegal channels. This is important in the face of evidence that about half of the annual production of amphetamine and barbiturate drugs, or between 8 and 9 billion pills, *have been diverted to nonmedical use*.

Quoting, Senator Dodd, Cong. Rec., Senate, 996 (January 24, 1970) (emphasis added).

The debate changed little as it moved to the House. The primary difference was that the House expanded the legislation to include drug research, education and treatment, in addition to the Senate's narrower focus upon the prevention of drug trafficking and diversion. The entire debate remained, however, in the context of the drug problem:

> There are a limited number of approaches to attack this problem—preventive steps, aimed at stopping experimentation before it starts; control, to regulate the supply and availability of drugs; rehabilitation to lead individuals away from drug dependence and addiction. It is my conviction that the Federal Government must make a concentrated effort in all of these areas.

Quoting, Representative Boland, Cong. Rec., House, 33315 (September 23, 1970).

> The word "control" in the title, of course, simply means enforcement by the Justice Department in *problems related to drug abuse*, by any person or corporation whether a manufacturer, wholesaler, or retailer. These controls cover all the hard narcotics and opiates, marijuana, and hallucinogens such as LSD, amphetamines, barbiturates, and even any tranquilizers subject to abuse.

Quoting, Representative Randall, Cong. Rec., House, 33656 (September 24, 1970) (emphasis added).

Here again, nothing from the 1970 House floor debate remotely suggests that Congress intended the Attorney General to determine the "legitimacy of medicine," or to establish medical policy in the states. To better control the rampant drug problem,

the House expanded the reach of the CSA to include drug research, education, treatment, and rehabilitation, but included not a word about regulating medical practice. The relevant language in the proposed legislation did not significantly change when it returned to the Senate later that same year:

> I am particularly grateful that the basic Controlled Dangerous Substances Act was passed in almost its entirety by the House. There were a number of minor disagreements; but more than 90 percent of the law which was reported by the Senate Subcomittee [sic] on Juvenile Delinquency will soon become the law of the land.
>
> This is no mean achievement. The Senate legislation passed the very close scrutiny of the House[,] which investigated the bill for many months. No significant changes were made, a procedure which does not often occur in bills sent over from the Senate.

Quoting, Senator Dodd, Cong. Rec., Senate, 35051, 35052 (October 6, 1970).

The 1984 amendments reveal that once again Congress was concerned about a rampant drug abuse problem, the diversion of otherwise lawful drugs to illicit or recreational uses. The bill was named the Dangerous Drug Diversion Control Act of 1984 and it was described as follows:

> Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5656) to amend the Controlled Substances Act *to strengthen the authority to prevent diversion of controlled substances*, and for other purposes, as amended.

Quoting, Representative Hughes, Cong. Rec., House, 25846 (September 18, 1984) (emphasis added).

> This bill addresses one of the most critical areas of drug abuse, the abuse of prescription drugs. Prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse. But I am sorry to say this aspect of drug abuse, *the diversion problem*, has often failed to get the societal or the enforcement attention that it deserves.

Quoting, Representative Hughes, Cong. Rec., House, 25848 (September 18, 1984) (emphasis added). The Attorney General would likely take the above "deaths and injuries" phrase out of context, just as he does in his petition (*see*, Pet. Cert. 22-23--"misuse of a drug in suicides and attempted suicides"), but the Congress was only concerned with illicit use, particularly that flowing from "diversion":

> *Diversion* is the connotation for the various means by which legitimate medical controlled substances are diverted from proper use to improper use. Invalid

prescriptions and pharmacy robberies are two types of retail level *diversion*. While much of the drug enforcement focus has been placed on the interdiction of improperly imported substances, *the problem of domestic diversion has quietly grown to staggering proportions*.

* * * . Abuse of prescription drugs through *diversion* at the manufacturing and distribution levels [is] severely curtailed under the current law by DEA. The vast majority of *diversions* occur at the retail level. * * * .

* * * * *

* * * . *This bill provides the Drug Enforcement Agency with the necessary tools to join State agencies in reducing diversion.*

Quoting, Representative Sawyer, Cong. Rec., House, 25849 (September 18, 1984) (emphasis added).

> Mr. Speaker, I rise in strong support of H.R. 5656, the *Dangerous Drug Diversion Control Act* of 1984. The bill amends the Controlled Substances Act to attempt *to prevent the diversion of controlled substances* from legitimate channels of medical distribution and administration to illegitimate channels for purposes of abuse. Evidence suggests that prescription drugs *diverted* by legitimate medical distributors to the illicit drug market account for about three-fourths of deaths and injuries due to drug abuse.

Quoting, Representative Gilman, Cong. Rec., House, 25851 (September 18, 1984) (emphasis added).

In sum, whether reviewing the 1970 or the 1984 legislative history, it is clear that the CSA was intended as a solution to the problems of illicit drug use, drug trafficking, and drug diversion. The CSA was never intended to empower the Attorney General to rule upon the legitimacy of medical practice in the States.

8. *The Attorney General fails to allege a single incident of illicit drug use, drug trafficking, or drug diversion*

Contrary to the requirements of the CSA and the expectations of Congress, the record in the instant case is entirely devoid of any evidence or even an allegation of illicit drug use, drug trafficking, or drug diversion. There are, for example, none of the usual allegations that banned drugs are being used, or that physicians practicing under the Oregon law are diverting otherwise lawful drugs to an illicit use. Large quantities are not prescribed, large numbers of prescriptions are not issued, patients are not instructed to fill their prescriptions at different drug stores, prescriptions are not issued for one person but privately intended for another, prescriptions are neither issued nor filled to satisfy the cravings of an addict, multiple prescriptions are not "spread out" to avoid detection, and practitioners are not accused of using street slang. In an apparent attempt to overcome this shortcoming, the Attorney General argues that, "the taking of drugs to commit suicide is drug abuse" (Pet. Cert., 23), but this is merely an

incomplete and argumentative statement of the issue, and not the "serious, thoughtful examination" of the issue that this Court observed in *Glucksberg*, *supra*, 521 U.S. at 719.

CONCLUSION

While this litigation may present interesting policy questions, in view of the plain language of the relevant statutes and the extensive legislative history, the legal questions are relatively simple. DEA registrants practicing pursuant to Oregon statutory and regulatory law are acting in the course of their professional practice, consistent with the terms of the CSA. The Attorney General's contrary interpretation of this same statutory scheme seeks to accomplish too much. *Raygor v. Regents of University of Minnesota*, 534 U.S. 533, 543 (2002) ("When Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute").

FOR THE FOREGOING REASONS, Peter A. Rasmussen, M.D., and David M. Hochhalter, Rph, urge that the Attorney General's petition be denied.

Respectfully submitted,

ELI D. STUTSMAN
Counsel of Record
621 SW Morrison
Thirteenth Floor
Portland, OR 97205
(503) 274-4048

January 10, 2005

APPENDIX

APPENDIX

The Oregon Death With Dignity Act 1

The Oregon Assisted Suicide Statute 21

Affidavit of Peter A. Rasmussen, M.D. 22

Affidavit of David M. Hochhalter, RPh 28

Affidavit of David M. Hochhalter, RPh 31

THE OREGON DEATH WITH DIGNITY ACT
(General Provisions)

(Section 1)

Note: The division headings, subdivision headings and leadlines for 127.800 to 127.890, 127.895 and 127.897 were enacted as part of Ballot Measure 16 (1994) and were not provided by Legislative Counsel.

127.800 §1.01. Definitions. The following words and phrases, whenever used in ORS 127.800 to 127.897, have the following meanings:

(1) "Adult" means an individual who is 18 years of age or older.

(2) "Attending physician" means the physician who has primary responsibility for the care of the patient and treatment of the patient's terminal disease.

(3) "Capable" means that in the opinion of a court or in the opinion of the patient's attending physician or consulting physician, psychiatrist or psychologist, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating if those persons are available.

(4) "Consulting physician" means a physician who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding the patient's disease.

(5) "Counseling" means one or more consultations as necessary between a state licensed psychiatrist or psychologist and a patient for the purpose of determining that the patient is capable and not suffering from a psychiatric or psychological disorder or depression causing impaired judgment.

(6) "Health care provider" means a person licensed, certified or otherwise authorized or permitted by the law of this state to administer health care or dispense medication in the ordinary course of business or practice of a profession, and includes a health care facility.

(7) "Informed decision" means a decision by a qualified patient, to request and obtain a prescription to end his or her life in a humane and dignified manner, that is based on an appreciation of the relevant facts and after being fully informed by the attending physician of:

(a) His or her medical diagnosis;

(b) His or her prognosis;

(c) The potential risks associated with taking the medication to be prescribed;

(d) The probable result of taking the medication to be prescribed; and

(e) The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control.

(8) "Medically confirmed" means the medical opinion of the attending physician has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records.

(9) "Patient" means a person who is under the care of a physician.

(10) "Physician" means a doctor of medicine or osteopathy licensed to practice medicine by the Board of Medical Examiners for the State of Oregon.

(11) "Qualified patient" means a capable adult who is a resident of Oregon and has satisfied the requirements of ORS 127.800 to 127.897 in order to obtain a prescription for medication to end his or her life in a humane and dignified manner.

(12) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months. [1995 c.3 §1.01; 1999 c.423 §1]

(Written Request for Medication to End One's Life in a Humane and Dignified Manner)

(Section 2)

127.805 §2.01. Who may initiate a written request for medication. (1) An adult who is capable, is a resident of Oregon, and has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and

who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with ORS 127.800 to 127.897.

(2) No person shall qualify under the provisions of ORS 127.800 to 127.897 solely because of age or disability. [1995 c.3 §2.01; 1999 c.423 §2]

127.810 §2.02. Form of the written request. (1) A valid request for medication under ORS 127.800 to 127.897 shall be in substantially the form described in ORS 127.897, signed and dated by the patient and witnessed by at least two individuals who, in the presence of the patient, attest that to the best of their knowledge and belief the patient is capable, acting voluntarily, and is not being coerced to sign the request.

(2) One of the witnesses shall be a person who is not:

(a) A relative of the patient by blood, marriage or adoption;

(b) A person who at the time the request is signed would be entitled to any portion of the estate of the qualified patient upon death under any will or by operation of law; or

(c) An owner, operator or employee of a health care facility where the qualified patient is receiving medical treatment or is a resident.

(3) The patient's attending physician at the time the request is signed shall not be a witness.

(4) If the patient is a patient in a long term care facility at the time the written request is made, one of the witnesses shall be an individual designated by the facility and having the qualifications specified by the Department of Human Services by rule. [1995 c.3 §2.02]

(Safeguards)

(Section 3)

127.815 §3.01. Attending physician responsibilities. (1) The attending physician shall:

(a) Make the initial determination of whether a patient has a terminal disease, is capable, and has made the request voluntarily;

(b) Request that the patient demonstrate Oregon residency pursuant to ORS 127.860;

(c) To ensure that the patient is making an informed decision, inform the patient of:

(A) His or her medical diagnosis;

(B) His or her prognosis;

(C) The potential risks associated with taking the medication to be prescribed;

(D) The probable result of taking the medication to be prescribed; and

(E) The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control;

(d) Refer the patient to a consulting physician for medical confirmation of the diagnosis, and for a determination that the patient is capable and acting voluntarily;

(e) Refer the patient for counseling if appropriate pursuant to ORS 127.825;

(f) Recommend that the patient notify next of kin;

(g) Counsel the patient about the importance of having another person present when the patient takes the medication prescribed pursuant to ORS 127.800 to 127.897 and of not taking the medication in a public place;

(h) Inform the patient that he or she has an opportunity to rescind the request at any time and in any manner, and offer the patient an opportunity to rescind at the end of the 15 day waiting period pursuant to ORS 127.840;

(i) Verify, immediately prior to writing the prescription for medication under ORS 127.800 to 127.897, that the patient is making an informed decision;

(j) Fulfill the medical record documentation requirements of ORS 127.855;

(k) Ensure that all appropriate steps are carried out in accordance with ORS 127.800 to 127.897 prior to writing a

prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner; and

(l)(A) Dispense medications directly, including ancillary medications intended to facilitate the desired effect to minimize the patient's discomfort, provided the attending physician is registered as a dispensing physician with the Board of Medical Examiners, has a current Drug Enforcement Administration certificate and complies with any applicable administrative rule; or

(B) With the patient's written consent:

(i) Contact a pharmacist and inform the pharmacist of the prescription; and

(ii) Deliver the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician or an expressly identified agent of the patient.

(2) Notwithstanding any other provision of law, the attending physician may sign the patient's death certificate. [1995 c.3 §3.01; 1999 c.423 §3]

127.820 §3.02. Consulting physician confirmation. Before a patient is qualified under ORS 127.800 to 127.897, a consulting physician shall examine the patient and his or her relevant medical records and confirm, in writing, the attending physician's diagnosis that the patient is suffering from a terminal disease, and verify that the patient is capable, is acting voluntarily and has made an informed decision. [1995 c.3 §3.02]

127.825 §3.03. Counseling referral. If in the opinion of the attending physician or the consulting physician a patient may be suffering from a psychiatric or psychological disorder or depression causing impaired judgment, either physician shall refer the patient for counseling. No medication to end a patient's life in a humane and dignified manner shall be prescribed until the person performing the counseling determines that the patient is not suffering from a psychiatric or psychological disorder or depression causing impaired judgment. [1995 c.3 §3.03; 1999 c.423 §4]

127.830 §3.04. Informed decision. No person shall receive a prescription for medication to end his or her life in a humane and dignified manner unless he or she has made an informed decision as defined in ORS 127.800 (7). Immediately prior to writing a prescription for medication under ORS 127.800 to 127.897, the attending physician shall verify that the patient is making an informed decision. [1995 c.3 §3.04]

127.835 §3.05. Family notification. The attending physician shall recommend that the patient notify the next of kin of his or her request for medication pursuant to ORS 127.800 to 127.897. A patient who declines or is unable to notify next of kin shall not have his or her request denied for that reason. [1995 c.3 §3.05; 1999 c.423 §6]

127.840 §3.06. Written and oral requests. In order to receive a prescription for medication to end his or her life in a humane and dignified manner, a qualified patient shall have made an oral request and a written request, and reiterate the oral request to his or her attending physician no less than fifteen (15) days after making the initial oral request. At the time the

qualified patient makes his or her second oral request, the attending physician shall offer the patient an opportunity to rescind the request. [1995 c.3 §3.06]

127.845 §3.07. Right to rescind request. A patient may rescind his or her request at any time and in any manner without regard to his or her mental state. No prescription for medication under ORS 127.800 to 127.897 may be written without the attending physician offering the qualified patient an opportunity to rescind the request. [1995 c.3 §3.07]

127.850 §3.08. Waiting periods. No less than fifteen (15) days shall elapse between the patient's initial oral request and the writing of a prescription under ORS 127.800 to 127.897. No less than 48 hours shall elapse between the patient's written request and the writing of a prescription under ORS 127.800 to 127.897. [1995 c.3 §3.08]

127.855 §3.09. Medical record documentation requirements. The following shall be documented or filed in the patient's medical record:

(1) All oral requests by a patient for medication to end his or her life in a humane and dignified manner;

(2) All written requests by a patient for medication to end his or her life in a humane and dignified manner;

(3) The attending physician's diagnosis and prognosis, determination that the patient is capable, acting voluntarily and has made an informed decision;

(4) The consulting physician's diagnosis and prognosis, and verification that the patient is capable, acting voluntarily and has made an informed decision;

(5) A report of the outcome and determinations made during counseling, if performed;

(6) The attending physician's offer to the patient to rescind his or her request at the time of the patient's second oral request pursuant to ORS 127.840; and

(7) A note by the attending physician indicating that all requirements under ORS 127.800 to 127.897 have been met and indicating the steps taken to carry out the request, including a notation of the medication prescribed. [1995 c.3 §3.09]

127.860 §3.10. Residency requirement. Only requests made by Oregon residents under ORS 127.800 to 127.897 shall be granted. Factors demonstrating Oregon residency include but are not limited to:

(1) Possession of an Oregon driver license;

(2) Registration to vote in Oregon;

(3) Evidence that the person owns or leases property in Oregon; or

(4) Filing of an Oregon tax return for the most recent tax year. [1995 c.3 §3.10; 1999 c.423 §8]

127.865 §3.11. Reporting requirements. (1)(a) The Department of Human Services shall annually review a sample of records maintained pursuant to ORS 127.800 to 127.897.

(b) The department shall require any health care provider upon dispensing medication pursuant to ORS 127.800 to 127.897 to file a copy of the dispensing record with the department.

(2) The department shall make rules to facilitate the collection of information regarding compliance with ORS 127.800 to 127.897. Except as otherwise required by law, the information collected shall not be a public record and may not be made available for inspection by the public.

(3) The department shall generate and make available to the public an annual statistical report of information collected under subsection (2) of this section. [1995 c.3 §3.11; 1999 c.423 §9; 2001 c.104 §40]

127.870 §3.12. Effect on construction of wills, contracts and statutes. (1) No provision in a contract, will or other agreement, whether written or oral, to the extent the provision would affect whether a person may make or rescind a request for medication to end his or her life in a humane and dignified manner, shall be valid.

(2) No obligation owing under any currently existing contract shall be conditioned or affected by the making or rescinding of a request, by a person, for medication to end his or her life in a humane and dignified manner. [1995 c.3 §3.12]

127.875 §3.13. Insurance or annuity policies. The sale, procurement, or issuance of any life, health, or accident insurance or annuity policy or the rate charged for any policy shall not be conditioned upon or affected by the making or rescinding of a request, by a person, for medication to end his or her life in a humane and dignified manner. Neither shall a qualified patient's act of ingesting medication to end his or her life in a humane and dignified manner have an effect upon a life, health, or accident insurance or annuity policy. [1995 c.3 §3.13]

127.880 §3.14. Construction of Act. Nothing in ORS 127.800 to 127.897 shall be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing or active euthanasia. Actions taken in accordance with ORS 127.800 to 127.897 shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law. [1995 c.3 §3.14]

(Immunities and Liabilities)

(Section 4)

127.885 §4.01. Immunities; basis for prohibiting health care provider from participation; notification; permissible sanctions. Except as provided in ORS 127.890:

(1) No person shall be subject to civil or criminal liability or professional disciplinary action for participating in good faith compliance with ORS 127.800 to 127.897. This includes being present when a qualified patient takes the

prescribed medication to end his or her life in a humane and dignified manner.

(2) No professional organization or association, or health care provider, may subject a person to censure, discipline, suspension, loss of license, loss of privileges, loss of membership or other penalty for participating or refusing to participate in good faith compliance with ORS 127.800 to 127.897.

(3) No request by a patient for or provision by an attending physician of medication in good faith compliance with the provisions of ORS 127.800 to 127.897 shall constitute neglect for any purpose of law or provide the sole basis for the appointment of a guardian or conservator.

(4) No health care provider shall be under any duty, whether by contract, by statute or by any other legal requirement to participate in the provision to a qualified patient of medication to end his or her life in a humane and dignified manner. If a health care provider is unable or unwilling to carry out a patient's request under ORS 127.800 to 127.897, and the patient transfers his or her care to a new health care provider, the prior health care provider shall transfer, upon request, a copy of the patient's relevant medical records to the new health care provider.

(5)(a) Notwithstanding any other provision of law, a health care provider may prohibit another health care provider from participating in ORS 127.800 to 127.897 on the premises of the prohibiting provider if the prohibiting provider has notified the health care provider of the prohibiting provider's

policy regarding participating in ORS 127.800 to 127.897. Nothing in this paragraph prevents a health care provider from providing health care services to a patient that do not constitute participation in ORS 127.800 to 127.897.

(b) Notwithstanding the provisions of subsections (1) to (4) of this section, a health care provider may subject another health care provider to the sanctions stated in this paragraph if the sanctioning health care provider has notified the sanctioned provider prior to participation in ORS 127.800 to 127.897 that it prohibits participation in ORS 127.800 to 127.897:

(A) Loss of privileges, loss of membership or other sanction provided pursuant to the medical staff bylaws, policies and procedures of the sanctioning health care provider if the sanctioned provider is a member of the sanctioning provider's medical staff and participates in ORS 127.800 to 127.897 while on the health care facility premises, as defined in ORS 442.015, of the sanctioning health care provider, but not including the private medical office of a physician or other provider;

(B) Termination of lease or other property contract or other nonmonetary remedies provided by lease contract, not including loss or restriction of medical staff privileges or exclusion from a provider panel, if the sanctioned provider participates in ORS 127.800 to 127.897 while on the premises of the sanctioning health care provider or on property that is owned by or under the direct control of the sanctioning health care provider; or

(C) Termination of contract or other nonmonetary remedies provided by contract if the sanctioned provider

participates in ORS 127.800 to 127.897 while acting in the course and scope of the sanctioned provider's capacity as an employee or independent contractor of the sanctioning health care provider. Nothing in this subparagraph shall be construed to prevent:

(i) A health care provider from participating in ORS 127.800 to 127.897 while acting outside the course and scope of the provider's capacity as an employee or independent contractor; or

(ii) A patient from contracting with his or her attending physician and consulting physician to act outside the course and scope of the provider's capacity as an employee or independent contractor of the sanctioning health care provider.

(c) A health care provider that imposes sanctions pursuant to paragraph (b) of this subsection must follow all due process and other procedures the sanctioning health care provider may have that are related to the imposition of sanctions on another health care provider.

(d) For purposes of this subsection:

(A) "Notify" means a separate statement in writing to the health care provider specifically informing the health care provider prior to the provider's participation in ORS 127.800 to 127.897 of the sanctioning health care provider's policy about participation in activities covered by ORS 127.800 to 127.897.

(B) "Participate in ORS 127.800 to 127.897" means to perform the duties of an attending physician pursuant to ORS

127.815, the consulting physician function pursuant to ORS 127.820 or the counseling function pursuant to ORS 127.825. "Participate in ORS 127.800 to 127.897" does not include:

(i) Making an initial determination that a patient has a terminal disease and informing the patient of the medical prognosis;

(ii) Providing information about the Oregon Death with Dignity Act to a patient upon the request of the patient;

(iii) Providing a patient, upon the request of the patient, with a referral to another physician; or

(iv) A patient contracting with his or her attending physician and consulting physician to act outside of the course and scope of the provider's capacity as an employee or independent contractor of the sanctioning health care provider.

(6) Suspension or termination of staff membership or privileges under subsection (5) of this section is not reportable under ORS 441.820. Action taken pursuant to ORS 127.810, 127.815, 127.820 or 127.825 shall not be the sole basis for a report of unprofessional or dishonorable conduct under ORS 677.415 (2) or (3).

(7) No provision of ORS 127.800 to 127.897 shall be construed to allow a lower standard of care for patients in the community where the patient is treated or a similar community. [1995 c.3 §4.01; 1999 c.423 §10]

Note: As originally enacted by the people, the leadline to section 4.01 read "Immunities." The remainder of the leadline was added by editorial action.

127.890 §4.02. Liabilities. (1) A person who without authorization of the patient willfully alters or forges a request for medication or conceals or destroys a rescission of that request with the intent or effect of causing the patient's death shall be guilty of a Class A felony.

(2) A person who coerces or exerts undue influence on a patient to request medication for the purpose of ending the patient's life, or to destroy a rescission of such a request, shall be guilty of a Class A felony.

(3) Nothing in ORS 127.800 to 127.897 limits further liability for civil damages resulting from other negligent conduct or intentional misconduct by any person.

(4) The penalties in ORS 127.800 to 127.897 do not preclude criminal penalties applicable under other law for conduct which is inconsistent with the provisions of ORS 127.800 to 127.897. [1995 c.3 §4.02]

127.892 Claims by governmental entity for costs incurred. Any governmental entity that incurs costs resulting from a person terminating his or her life pursuant to the provisions of ORS 127.800 to 127.897 in a public place shall have a claim against the estate of the person to recover such costs and reasonable attorney fees related to enforcing the claim. [1999 c.423 §5a]

(Severability)

(Section 5)

127.895 §5.01. Severability. Any section of ORS 127.800 to 127.897 being held invalid as to any person or circumstance shall not affect the application of any other section of ORS 127.800 to 127.897 which can be given full effect without the invalid section or application. [1995 c.3 §5.01]

(Form of the Request)

(Section 6)

127.897 §6.01. Form of the request. A request for a medication as authorized by ORS 127.800 to 127.897 shall be in substantially the following form:

REQUEST FOR MEDICATION
TO END MY LIFE IN A HUMANE
AND DIGNIFIED MANNER

I, _____, am an adult of sound mind.

I am suffering from _____, which my attending physician has determined is a terminal disease and which has been medically confirmed by a consulting physician.

I have been fully informed of my diagnosis, prognosis, the nature of medication to be prescribed and potential associated

risks, the expected result, and the feasible alternatives, including comfort care, hospice care and pain control.

I request that my attending physician prescribe medication that will end my life in a humane and dignified manner.

INITIAL ONE:

_____ I have informed my family of my decision and taken their opinions into consideration.

_____ I have decided not to inform my family of my decision.

_____ I have no family to inform of my decision.

I understand that I have the right to rescind this request at any time.

I understand the full import of this request and I expect to die when I take the medication to be prescribed. I further understand that although most deaths occur within three hours, my death may take longer and my physician has counseled me about this possibility.

I make this request voluntarily and without reservation, and I accept full moral responsibility for my actions.

Signed: _____

Dated: _____

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) Is personally known to us or has provided proof of identity;

(b) Signed this request in our presence;

(c) Appears to be of sound mind and not under duress, fraud or undue influence;

(d) Is not a patient for whom either of us is attending physician.

_____Witness 1/Date

_____Witness 2/Date

NOTE: One witness shall not be a relative (by blood, marriage or adoption) of the person signing this request, shall not be entitled to any portion of the person's estate upon death and shall not own, operate or be employed at a health care facility where the person is a patient or resident. If the patient is an inpatient at a health care facility, one of the witnesses shall be an individual designated by the facility.

163.125 Manslaughter in the second degree. (1) Criminal homicide constitutes manslaughter in the second degree when:

(a) It is committed recklessly;

(b) A person intentionally causes or aids another person to commit suicide [underscore added]; or

(c) A person, with criminal negligence, causes the death of a child under 14 years of age or a dependent person, as defined in ORS 163.205, and:

(A) The person has previously engaged in a pattern or practice of assault or torture of the victim or another child under 14 years of age or a dependent person; or

(B) The person causes the death by neglect or maltreatment, as defined in ORS 163.115.

(2) Manslaughter in the second degree is a Class B felony. [1971 c.743 §89; 1975 c.577 §3; 1997 c.850 §4; 1999 c.954 §1]

AFFIDAVIT OF PETER A. RASMUSSEN, M.D., IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT FILED BY PETER A. RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh

STATE OF OREGON)
) ss.
County of Marion)

I, Peter A. Rasmussen, M.D., being duly sworn, make this affidavit based on personal knowledge in support of summary judgment in my favor, as follows:

1. I am a medical oncologist licensed to practice medicine in the State of Oregon. I am Board Certified in Hospice and Palliative Medicine.

2. I am also registered with the Drug Enforcement Administration (DEA) and am authorized to prescribe and dispense controlled substances under both state and federal law.

3. As a medical oncologist and DEA registrant, I have treated terminally ill patients for 21 years in Oregon. I estimate that I am currently treating hundreds of patients facing a terminal disease.

4. Since passage of the Oregon Death With Dignity Act, I have received many requests from patients seeking information or assistance under the Act. As an attending physician and DEA registrant, I have participated under the Oregon Death With Dignity Act several times and, when appropriate under the Act, I have written prescriptions for controlled Substances, but not Schedule I substances. I have provided copies of my dispensing records to the Department of

Human Services as required under the Oregon Death With Dignity Act.

5. At the time of this affidavit, three of my patients have satisfied all of the requirements of the Oregon Death With Dignity Act. All three are qualified to obtain prescriptions under the Act. In order to preserve patient confidentiality, I will identify them by profile:

Patient A Patient A is a woman approximately 64 years old who is dying from ovarian cancer. She has satisfied all of the requirements necessary under Oregon law to obtain controlled substances to hasten her death.

Patient B Patient B is a man approximately 72 years old who is dying from lung cancer. He has satisfied all of the requirements necessary under Oregon law to obtain controlled substances to hasten his death.

Patient C Patient C is a woman approximately 52 years old who is also dying from ovarian cancer. She has satisfied all of the requirements necessary under Oregon law to obtain controlled substances to hasten her death.

6. I cannot predict whether any of these patients will choose to hasten their impending deaths, but all three are qualified under the law to do so. I am currently attending to their needs on an ongoing basis. For example, the prescription for Patient B has already been written and filled and I have the controlled substance in my possession should Patient B decide to use it.

7. Patients A and C both know of my role in this litigation. Both Patients A and C have expressed their support and appreciation for my willingness to represent their interests. For my patients that support the options available to them under

the Oregon Death With Dignity Act, I am intentionally representing their interests in this litigation.

8. Due to the nature of my practice, at any given time, many of my patients will be terminally ill and I will continue to receive requests from patients for prescriptions and information under the Oregon Death With Dignity Act.

9. Prior to court's issuance of a temporary restraining order, my ability to meet the community standard of care as established under Oregon law and practice was severely restricted. As the direct result of this court's preliminary injunctive relief, my ability to meet the community standard of care as established under Oregon law and practice has been restored.

10. As the attending physician under the Oregon Death With Dignity Act I am practicing legitimate medicine in the course of my professional practice. I comply with both state law and the standard of care when I fulfill the criteria of an "attending physician" as required by section 127.815 of the Act. For example, I make the initial determination of whether my patients have a terminal disease, are capable, and have made their request voluntarily. I ensure that my patients are informed by informing them of their medical diagnosis, prognosis, the potential risk and probable result associated with taking the medication to be prescribed, and the feasible alternatives, including, but not limited to, comfort care, hospice care and pain control.

11. I further refer my patients to a consulting physician for medical confirmation of the diagnosis, and for a second opinion that my patients are capable and acting voluntarily. When appropriate, I also refer my patients for counseling. I recommend that my patients notify their next of kin and counsel them about the importance of having another

person present when they take the medication prescribed under the Oregon Death With Dignity Act. I further inform my patients that they may change their minds at any time, in any manner, and I remind my patients of this right throughout the process, including immediately prior to writing the prescription, at which point I again confirm that the patient is again making an informed decision.

12. As required under the Oregon Death With Dignity Act, I dispense the medications directly, including ancillary medications intended to facilitate the desired effect and minimize any discomfort. Or, in the alternative, I contact a pharmacist and inform the pharmacist of the prescription. I then deliver the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, to me as the attending physician, or the patient's chosen representative. I am at all times registered as a dispensing physician with the Board of Medical Examiners and I have a current Drug Enforcement Administration certificate.

13. I further satisfy all the statutory medical record documentation requirements and provide a copy of my dispensing record to the Department of Human Services. In general, I ensure that all appropriate steps are carried out in accordance with ORS 127.800 to 127.897 prior to writing a prescription for medication to enable a qualified patient to hasten his or her death. I comply with all the provisions of the Oregon Death With Dignity Act. I never engage in drug trafficking or diversion. As a physician practicing under the Oregon Death With Dignity Act, I am practicing legitimate medicine in the course of my professional practice.

14. I encourage this court to award summary judgment in my favor so that I may continue to meet my patients needs under Oregon statutory law, regulatory law, and

the community standard of care established in the State of Oregon.

15. As a physician, I encourage patients to be in charge of their own care. An important part of what a physician does is to describe options and counsel patients on these options. Depriving me of the ability to participate under the Oregon Death With Dignity Act reduces the number of options available to my patients and will lead to unnecessary suffering for terminally ill patients.

16. If the DEA enforcement promise i[s] not enjoined, I will need to inform my patients that I cannot risk participation under the Oregon Death With Dignity Act. Due to Attorney General John Ashcroft's directive to enforce the Controlled Substances Act against physicians like myself practicing in accord with Oregon law and the community standard of care, and in the absence of a permanent injunction, I will no longer be able to meet the community standard of care as established under Oregon law and practice. I cannot risk DEA registration revocation proceedings or other sanctions, criminal and financial. I cannot risk my ability to practice as a medical oncologist, which has provided my livelihood for 21 years. Nor can I risk my family's security, or my ability to provide for my family.

17. In the absence of a permanent injunction, the Oregon Death With Dignity Act will be rendered useless. Only controlled substances are suitable for use under the Oregon Death With Dignity Act; they are used for what Oregon has determined to be a legitimate medical purpose in the normal course of medical practice in Oregon. These controlled substances are prescribed by physicians and dispensed by pharmacies for other purposes as well. Prescriptions for controlled substances under the Oregon Death With Dignity Act

are written by state-licensed physicians and filled by state-licensed pharmacists, in full compliance with the closed system of procedures established by the CSA and enforced by the DEA. These drugs are not otherwise available.

18. Time is important and admittedly short for my patients. Some of my patients face particularly dire circumstances. Once they are qualified to receive a prescription under the Oregon Death With Dignity Act they are by definition "terminally ill," having six months or less to live. Consequently, there will be only a short period of time before they lose their competency, ability to self-administer, or die from their underlying disease. For my patients, and others patients similarly situated, DEA enforcement should be permanently enjoined.

DATED this __ day of January, 2002.

_____
Peter A. Rasmussen, M.D.

SUBSCRIBED AND SWORN TO before me this ___ day of January, 2002.

_____
NOTARY PUBLIC FOR OREGON
My Commission Expires: _____

AFFIDAVIT OF DAVID M. HOCHHALTER, RPh IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT FILED BY PETER A. RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh

STATE OF OPEGON)
) ss.
County of Marion)

I, David M. Hochhalter, RPh, being duly sworn, make this affidavit based on personal knowledge in support of summary judgment in my favor, as follows:

1. I am a pharmacist licensed to practice in the State of Oregon. I have been a pharmacist for almost 23 years. I also own a pharmacy that is registered with the Drug Enforcement Administration (DEA). I am authorized to possess and dispense controlled substances under both state and federal law.

2. As a licensed Oregon pharmacist and DEA registrant, I dispense controlled substances in Oregon.

3. As a licensed Oregon pharmacist and DEA registrant, I have previously filled prescriptions under the Oregon Death with Dignity Act working in conjunction with Dr. Peter Rasmussen. I have filled prescriptions for Dr. Rasmussen during the pendency of this litigation, as recently as last week.

4. As a licensed Oregon pharmacist and DEA registrant, I will continue to fill prescriptions written by Dr. Rasmussen under the Oregon Death With Dignity Act.

5. In the absence of a permanent injunction, the Oregon Death With Dignity Act will be rendered useless. Only controlled substances are suitable for use under the Oregon Death With Dignity Act; they are used for what Oregon has determined to be a legitimate medical purpose in the normal course of medical practice in Oregon. These controlled substances are prescribed by physicians and dispensed by pharmacies for other purposes as well. Prescriptions for controlled substances under the Oregon Death with Dignity Act are written by state-licensed physicians and filled by state-licensed pharmacists, in full compliance with the closed system of procedures established by the CSA. These drugs are not otherwise available. I never engage in drug trafficking or diversion. As a pharmacist dispensing under the Oregon Death With Dignity Act, I am practicing legitimate medicine in the normal course of my professional practice.

6. In the absence of a permanent injunction against Attorney General John Ashcroft's directive to the DEA to enforce the Controlled Substances Act against DEA registrants like myself, practicing in accord with Oregon law and the community standard of care, I can no longer participate under the Oregon Death With Dignity Act. If the court's temporary stay against DEA enforcement is not converted into a permanent injunction, I will need to inform Dr. Rasmussen and our patients that I cannot risk participation under the Oregon Death With Dignity Act. Even if Dr. Rasmussen were willing to write the prescriptions, I would be precluded from filling them because I cannot risk DEA registration revocation proceedings or other sanctions, criminal and financial. I cannot risk my livelihood, or my family's security.

DATED this __ day of January, 2002.

_____
David Malcom Hochhalter, RPh,

SUBSCRIBED AND SWORN TO before me this ___ day of January, 2002.

_____
NOTARY PUBLIC FOR OREGON
My Commission Expires: _____

STATE OF OREGON)
) ss.
County of Marion)

I, David M. Hochhalter, RPh, being duly sworn, make this affidavit based on personal knowledge in support of summary judgment in my favor, as follows:

1. I am a pharmacist licensed to practice in the State of Oregon. I have been a pharmacist for almost 23 years. I also own a pharmacy that is registered with the Drug Enforcement Administration (DEA). I am authorized to possess and dispense controlled substances under both state and federal law.

2. As a licensed Oregon pharmacist and DEA registrant, I dispense controlled substances in Oregon.

3. As a licensed Oregon pharmacist and DEA registrant, I have previously filled prescriptions under the Oregon Death with Dignity Act.

4. Based upon my personal experience and my knowledge of medical practice under the Oregon Death with Dignity Act, two drugs have been used to hasten a terminally ill patient's death, Seconal (9 grams), or Nembutal (10 grams). The full retail price is $68.55 for 9 grams of Seconal, and $133.55 for 10 grams of Nembutal. Seconal was the preferred drug until November of 2001 when supplies ran short. Since November of 2001, Nembutal has been used. I expect that

Seconal will once again be the preferred drug when supplies and inventories are restored to normal.

DATED this ___ day of April, 2002.

_____
David Malcom Hochhalter, RPh,

SUBSCRIBED AND SWORN TO before me this ___ day of April, 2002.

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No. 04-623

In the Supreme Court of the United States

JOHN D. ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

PAUL D. CLEMENT
Acting Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

TABLE OF AUTHORITIES

Cases:	Page
Alaska Dep't of Envtl. Conservation v. *EPA*, 540 U.S. 461 (2004)	9
Auer v. *Robbins*, 519 U.S. 452 (1997)	9
Barnhart v. *Walton*, 535 U.S. 212 (2002)	9
California Fed. Sav. & Loan Ass'n v. *Guerra*, 479 U.S. 272 (1987)	5
Christensen v. *Harris County*, 529 U.S. 576 (2000)	9
City of Edmonds v. *Oxford House, Inc.*, 514 U.S. 725 (1995)	2
Gately v. *Massachusetts*, 2 F.3d 1221 (1st Cir. 1993), cert. denied, 511 U.S. 1082 (1994)	3
Gooding v. *United States*, 416 U.S. 430 (1974)	7
Gregory v. *Ashcroft*, 501 U.S. 452 (1974)	1
Hodel v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264 (1981)	5
Jerome v. *United States*, 318 U.S. 101 (1943)	2
Kane v. *Kulongoski*, 871 P.2d 993 (Or. 1994)	6
Linder v. *United States*, 268 U.S. 5 (1925)	4
Minor v. *United States*, 396 U.S. 87 (1969)	3
Mississippi Band of Choctaw Indians v. *Holyfield*, 490 U.S. 30 (1989)	2, 7
Raygor v. *Regents of the Univ. of Minn.*, 534 U.S. 533 (2002)	2, 3
Reina v. *United States*, 364 U.S. 507 (1960)	3
Solid Waste Agency v. *Army Corps of Eng'rs*, 531 U.S. 159 (2001)	3
Thomas Jefferson Univ. v. *Shalala*, 512 U.S. 504 (1994)	9
United States v. *Darby*, 312 U.S. 100 (1941)	4
United States v. *Lot 5, Fox Grove*, 23 F.3d 359 (11th Cir. 1994), cert. denied, 513 U.S. 1076 (1995)	3
United States v. *Mead Corp.*, 533 U.S. 218 (2001)	9
United States v. *Moore*, 423 U.S. 122 (1975)	4, 7, 8, 9
United States v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001)	4, 6, 7

Constitution, statutes and regulation:	Page
U.S. Const.:	
Commerce Clause	3
Supremacy Clause	6
Controlled Substances Act:	
21 U.S.C. 801 *et seq.*	1
21 U.S.C. 823(a)(1)	8
21 U.S.C. 829	9
21 C.F.R.:	
Section 1306.04(a)	1, 9
Section 1308.12(b)(1)	8
Section 1308.12(b)(4)	8
Or. Rev. Stat. §§ 161.605 & 161.625 (2003)	6
Miscellaneous:	
American Medical Association, *Current Opinions of the Council of Ethical and Judicial Affairs, E-2.211, Physician-Assisted Suicide*, <http://www.ama-assn.org/ama/pub/category/print/8459.html> (last visited Jan. 24, 2005)>	10
H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1 (1970)	10
S. Rep. No. 225, 98th Cong., 1st Sess. (1983)	9

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STATE OF OREGON, ET AL.

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REPLY BRIEF FOR THE PETITIONERS

Since 1971, Department of Justice regulations implementing the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, have provided that a prescription for drugs covered by the Act is valid only if issued for a "legitimate medical purpose" as part of "professional treatment." 21 C.F.R. 1306.04(a). In 2001, the Attorney General issued an interpretive ruling to clarify that a prescription for the purpose of assisting an individual to commit suicide is not made for a "legitimate medical purpose" for "treatment" within the meaning of Section 1306.04(a). The court of appeals struck down the Attorney General's interpretive rule on the ground that the CSA does not contain "an 'unmistakably clear' indication * * * that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide." Pet. App. 12a. The petition demonstrates (Pet. 20-23) that the court of appeals' ruling represents a dramatic expansion of this Court's decision in *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991). The consequence of applying *Gregory*'s clear statement rule not just to statutes that implicate the

essential attributes of state sovereignty but to every federal statute that assertedly affects an area of traditional state regulation—even when a State stands alone in its policy judgment—would be to undermine the uniform application of national regulatory schemes by making their content dependent upon the vagaries of state law. That result cannot be squared with this Court's consistent application of the opposite presumption: "[I]n the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989) (quoting *Jerome* v. *United States*, 318 U.S. 101, 104 (1943)).

Respondents do nothing to allay concerns about the broad sweep of the court of appeals' ruling. To the contrary, they embrace it. The Court should grant certiorari to review the court of appeals' radical new rule regarding the interplay of state and federal law.

1. a. Oregon suggests that this Court's review is not warranted because the court of appeals' decision applies a purportedly "long-established" rule that "a clear statement of Congressional intent" is necessary whenever federal legislation would "displace" a State's policy in "an area traditionally and historically within the States' regulatory powers." Or. Br. in Opp. 12, 13. Oregon's reliance on *Gregory* for such a proposition (*id.* at 11) is wholly misplaced. *Gregory* stressed that a State's decision as to the qualifications for its own judges—*i.e.*, the composition of its own government—went "*beyond* an area traditionally regulated by the States," and was, rather, a "decision of the most fundamental sort for a sovereign entity." 501 U.S. at 460 (emphasis added). See *City of Edmonds* v. *Oxford House, Inc.*, 514 U.S. 725, 732 n.5 (1995) (emphasizing the same with respect to *Gregory*). *Raygor* v. *Regents of the University of Minnesota*, 534 U.S. 533 (2002), on which Oregon also relies

(Or. Br. in Opp. 11), similarly involved a fundamental characteristic of state sovereignty, the terms on which the State had consented to suit in its own courts. 534 U.S. at 544. Other courts of appeals, as the petition notes (Pet. 21), have rejected attempts to extend *Gregory* in the manner adopted by the Ninth Circuit and advocated by respondents. See *United States* v. *Lot 5, Fox Grove*, 23 F.3d 359, 362 (11th Cir. 1994), cert. denied, 513 U.S. 1076 (1995); *Gately* v. *Massachusetts*, 2 F.3d 1221, 1230 (1st Cir. 1993), cert. denied, 511 U.S. 1082 (1994).

b. Oregon also invokes (Or. Br. in Opp. 8, 12, 13, 17) a separate clear statement rule based on *Solid Waste Agency* v. *Army Corps of Engineers*, 531 U.S. 159 (2001), but that decision is likewise inapposite here. In *Solid Waste Agency*, the Court applied the doctrine of constitutional avoidance: "Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result." *Id.* at 172. The "significant constitutional question[]" avoided in *Solid Waste Agency* was whether application of the Clean Water Act to "nonnavigable, isolated, intrastate waters" would be within Congress's Commerce Clause authority. *Id.* at 172-173.

There is no similar constitutionally dubious application to be avoided here. Regulation of the distribution of controlled substances pursuant to the CSA does not "invoke[] the outer limits of Congress' power" or "push the limit of congressional authority" under the Commerce Clause. *Solid Waste Agency*, 531 U.S. at 172-173. This Court has repeatedly upheld federal regulation of the distribution of controlled substances by doctors and pharmacists as within Congress's Commerce Clause authority. *Minor* v. *United States*, 396 U.S. 87, 98 n.13 (1969) (ban on sale of narcotics is within Congress's constitutional power); *Reina* v. *United States*, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws"). See Gov't Br. 14-17, 20-22 and

Reply Br. 3-12, *Ashcroft* v. *Raich*, No. 03-1454 (argued Nov. 29, 2004).

Nor is there some independent constitutional limitation on Congress's power to legislate with respect to medical matters. The court of appeals cited *Linder* v. *United States*, 268 U.S. 5 (1925), as establishing a constitutional prohibition against Congress's legislating in a way that affects "control of medical practice in the states." Pet. App. 10a, 12a. As the petition explains (Pet. 22), however, *Linder* relied upon the *Lochner*-era doctrine that Congress could not employ its enumerated powers to accomplish general goals relating to health and welfare. See *Linder*, 268 U.S. at 17. That doctrine was expressly disavowed in *United States* v. *Darby*, 312 U.S. 100, 115-117 (1941). While respondents cite more recent cases that refer to the States' traditional role in regulating health and medicine (Or. Br. in Opp. 14-15; Rasmussen Br. in Opp. 15-16, 18), none of them suggests that there is a *constitutional* limitation on Congress's ability to exercise the full scope of its enumerated powers simply because it may have some effect on the practice of medicine. Indeed, this Court has applied the CSA in cases where its impact on the practice of medicine and state law was obvious without intimating the existence of any such constitutional limitation. *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 494-495 (2001) (CSA precludes recognition of a "medical necessity" defense for marijuana use, based on the recommendation of a physician, despite California's determination that marijuana has medical utility); *United States* v. *Moore*, 423 U.S. 122, 139 (1975) (upholding CSA conviction of physician for dispensing controlled substances from his medical practice).

c. Respondents' briefs in opposition confirm the potentially staggering breadth of the court of appeals' clear statement rule. Respondents affirmatively trumpet that under the court of appeals' ruling, a clear statement is required

whenever the federal statute or regulation in question involves an area that is "historically within the States' regulatory powers." Or. Br. in Opp. 13. See Rasmussen Br. in Opp. 15-18. Under that approach, virtually every federal regulation would need a clear statement from Congress, because "the States' regulatory powers" encompass everything not forbidden by the Constitution. *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 311 (1981) ("[T]he reserved police powers of the States * * * are plenary unless challenged as violating some specific provision of the Constitution."). Thus, far from establishing that the decision below is a narrow, fact-specific ruling, respondents' briefs underscore its breadth. The Ninth Circuit's departure from decisions of this Court and other courts of appeals on an issue so basic to the allocation of powers between Congress and the States warrants review by this Court.

2. Respondents also suggest (Or. Br. in Opp. 17-18; Rasmussen Br. in Opp. 15-17) that the court of appeals' decision can be supported as an application of the presumption against federal preemption of state law. See Pet. App. 14a-15a. That presumption is unavailing to respondents here because the Attorney General's interpretive ruling does not preempt Oregon's assisted suicide law. When a "state statute is pre-empted by federal law," it is thereby rendered "invalid under the Supremacy Clause of the Constitution." *California Fed. Sav. & Loan Ass'n* v. *Guerra*, 479 U.S. 272, 280 (1987). As Oregon concedes, however, the Attorney General's interpretive ruling "does not suggest that the [Oregon law] is invalid. He asserts only that his authority over controlled substances allows him to prevent * * * use [of such controlled substances] for purposes authorized by the Oregon law." Or. Br. in Opp. 9 n.7. On that point, Oregon is correct. Oregon's law remains valid and continues to have the effect of "exempt[ing] physicians who comply

with the provisions of the proposed measure from prosecution under [Or. Rev. Stat. §§ 161.605 and 161.625 (2003)]," which otherwise make it a state law felony for anyone, including a physician, to aid a suicide. *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994). Moreover, to the extent doctors in Oregon dispense substances other than those regulated under the CSA to hasten their patients' deaths, the Attorney General's interpretive ruling has no relevance whatsoever to their conduct.

Oregon's de-criminalization law for physician-assisted suicide is no more preempted than California's laws decriminalizing the possession and use of marijuana for medical purposes. But despite their ability to remove parallel and duplicative state-law prohibitions, States are not free to establish state-law exceptions to the federal-law duty to comply with the CSA. See *Oakland Cannabis*, 532 U.S. 494-495 (CSA precludes "medical necessity" defense, despite a California law recognizing marijuana's purported medical utility). The contrary rule that respondents urge would stand the Supremacy Clause on its head, presumptively "preempting" federal law whenever it conflicted with state law.

3. a. The court of appeals' holding that the Attorney General's interpretive rule exceeded his authority was thoroughly infected by its mistaken understanding of the proper framework of analysis and standard of review. For example, the court of appeals refused to defer to the Attorney General's construction of the CSA and implementing regulation because the court mistakenly believed, based on the serious errors discussed above, that the interpretive rule "exceeds the scope of the CSA and ignores the Attorney General's limited role," Pet. App. 22a, and that, under *Solid Waste Agency*, the court was free to "refuse[] to defer to [the Attorney General's] interpretation of its own regulations without clear authority from Congress," *id.* at 23a. Respondents cannot separate the court of appeals' ultimate holding from its flawed starting point.

b. Applying the proper framework of statutory construction and deference to administrative actions, the Attorney General's interpretive ruling is plainly valid. As the petition explains (Pet. 19), the appropriate presumption, even in cases that touch upon areas of traditional state regulation, such as child custody, is that a national federal regulatory scheme does not yield to or depend on state law. See *Mississippi Band of Choctaw Indians*, 490 U.S. at 43, 47. And specifically with respect to the CSA, this Court's precedents already establish that Congress intended the CSA to provide a "comprehensive federal scheme for the control of drug abuse." *Gooding* v. *United States*, 416 U.S. 430, 449 (1974). In *Moore*, the Court recognized that the CSA requires prescriptions to be made "in accordance with a standard of medical practice generally recognized and accepted in the United States." 423 U.S. at 139. And, more recently, in *Oakland Cannabis*, the Court rejected the claim that Californians using marijuana for medical purposes "upon the recommendation or approval of a physician" consistent with California law were thereby exempt from the prohibitions in the CSA, in light of the federal classification of marijuana as a Class I substance with no recognized medical use. 532 U.S. at 486, 490, 494-495.

Respondents' attempts to distinguish those cases are unavailing. Oregon maintains (Or. Br. in Opp. 16-17) that *Moore* is distinguishable because it arose from the District of Columbia, where there was no State law to apply. But nothing in the CSA distinguishes its application in the District of Columbia from elsewhere, and Oregon points to nothing in the Court's opinion to suggest that the site of the crime was relevant to the decision. Indeed, as pointed out in the petition (at 18 n.5), other courts of appeals, in conflict

with the decision below, have adhered to *Moore* and applied a national standard for professional practice under the CSA.

Respondents also suggest (Or. Br. in Opp. 16; Rasmussen Br. in Opp. 8; Patient Br. in Opp. 14) that *Oakland Cannabis* is distinguishable because that case dealt with a drug for which there was *no* accepted medical use. That argument simply ignores the central teaching of *Oakland Cannabis*—that it was the *federal* determination of medical utility that governed, not the contrary *state* determination. Respondents offer no basis in the statutory text for concluding that only the initial scheduling involves a federal determination as to a substance's utility for a legitimate and accepted medical purpose. On respondents' view, California could equally trump federal law with respect to opium and cocaine—Schedule II substances, 21 C.F.R. 1308.12(b)(1) and (4)—instead of marijuana. Indeed, in light of the Attorney General's responsibility under the CSA to ensure an "adequate * * * supply" of Schedule II substances "for legitimate medical * * * purposes," 21 U.S.C. 823(a)(1), the Attorney General would, under respondents' interpretation, be affirmatively *required* to ensure an adequate supply of such substances for whatever uses a particular State decided to recognize. There is nothing in the text of the CSA that requires such an anomalous result. *Moore*, which involved a Schedule II substance (methadone), is to the contrary. See 423 U.S. at 124.

c. Because the court of appeals concluded that state law should define "legitimate medical purpose" under the CSA, it did not address whether the Attorney General's interpretation was correct or entitled to deference as a matter of federal law. See Pet. App. 9a. We have already explained in the petition (at 11-13, 23-26) why the Attorney General's interpretive ruling is entirely reasonable and entitled to deference. Nonetheless, we briefly address a couple of additional points raised by respondents.

Contrary to the arguments of the patient respondents (Patient Br. in Opp. 9-10), this Court's decisions in *Alaska Department of Environmental Conservation* v. *EPA*, 540 U.S. 461 (2004); *Barnhart* v. *Walton*, 535 U.S. 212 (2002); *United States* v. *Mead Corp.*, 533 U.S. 218 (2001), and *Christensen* v. *Harris County*, 529 U.S. 576 (2000), do not justify decreased deference here. Each of those decisions involved an agency interpretation of statute, rather than an agency's interpretation of its own regulation, which is at issue here, and which is governed by the heightened deference standard stated in *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997), and *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994). Such deference is especially warranted in this case, because respondents do not challenge the validity of the regulation itself, which since 1971 has governed the determination of what prescriptions are valid under the CSA.*

Finally, respondents fail to cast any doubt on the reasonableness of the Attorney General's conclusion that assisting in bringing about a patient's suicide is not a "legitimate medical purpose" for "treatment" within the

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* Respondents contend (Or. Br. in Opp. 14 n.10; Patient Br. in Opp. 15-16) that the phrase "legitimate medical use" in Section 1306.04(a) must refer to state law because when the regulation was promulgated in 1971, the CSA required the Attorney General to defer to state regulators with respect to doctor registration. But Section 1306.04(a) does not address the registration of physicians. Rather, it is a substantive regulation addressing what constitutes a valid prescription under 21 U.S.C. 829, and specifying that distribution without a valid prescription violates the CSA. 21 C.F.R. 1306.04(a). As this Court's decision in *Moore* reflects, 423 U.S. at 139-141, the relevant standard under the CSA for accepted medical practice has always been understood as a national one. See also p. 7, *supra*. Moreover, contrary to Oregon's assertion (Or. Br. in Opp. 14 n.10), a doctor's registration could always be revoked for violation of the CSA, though, prior to 1984, this required that the doctor first be convicted of a violation. See S. Rep. No. 225, 98th Cong., 1st Sess. 266 (1983).

meaning of that regulation. Respondents cannot deny that the ethical guidelines of the American Medical Association specifically provide that "[p]hysician assisted suicide is fundamentally incompatible with the physician's role as healer," a view that is shared by 49 of the 50 states. American Medical Association, *Current Opinions of the Council of Ethical and Judicial Affairs, E-2.211, Physician-Assisted Suicide*, <http://www.ama-assn.org/ama/pub/category/print/8459.html> (last visited Jan. 24, 2005). Indeed, the legislative history of the CSA demonstrates that Congress itself regarded the use of controlled substances to commit suicide as a serious problem of drug abuse. See Pet. 23-24 (citing H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1 (1970)).

In short, without the court of appeals' fundamentally flawed reliance on clear statement rules and a presumption against preemption that have no application here under decisions of this Court and other courts of appeals, the court of appeals' holding cannot survive scrutiny.

* * * * *

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted.

PAUL D. CLEMENT
Acting Solicitor General

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RESPONDENTS.

On Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

BRIEF OF FOCUS ON THE FAMILY AND THE FAMILY RESEARCH COUNCIL AS *AMICI CURIAE*, SUPPORTING PETITIONERS

WILLIAM WAGNER
NELSON P. MILLER
Counsel of Record

COOLEY LAW SCHOOL
300 South Capitol
Lansing, MI 48933
(517) 371-5140

STEPHEN W. REED
35 N. Lake Ave.
Pasadena, CA 91101
(626) 449-4521

PATRICK A. TRUEMAN
801 G. Street NW
Washington D.C. 20001
(202) 393-2100

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF *AMICI CURIAE* 1

CONSENT TO FILE BRIEF 2

SUMMARY OF ARGUMENT 3

ARGUMENT 4

THE COURT OF APPEALS ERRED IN GRANTING OREGON'S REQUEST TO ENJOIN THE UNITED STATES FROM ENFORCING THE FEDERAL CONTROLLED SUBSTANCES ACT 4

A. Congress, Pursuant to its Enumerated Powers in Article I of the United States Constitution, May Regulate the Dispensing of Controlled Substances by Physicians and Other Medical Professionals 4

B. The Federal Controlled Substances Act Preempts the Oregon Law Authorizing Doctors to Dispense Drugs to Assist Killing a Human Being 7

C. Dispensing Controlled Substances to Assist Suicide Is Not a Traditional State Medical Practice Protected from Federal Regulation 12

D. The Attorney General Acted within His Statutory Authority 14

E. Enjoining the United States from Protecting the Citizenry against Dispensing Drugs to Kill a Person, Creates a Culture of Death with Serious Implications 19

CONCLUSION 24

TABLE OF AUTHORITIES

Cases:

Boggs v. Boggs, 520 U.S.833 (1997) 10

Gade v. National Solid Waste Management Assn., 505 U.S. 98 (1992) 10

Hisquierdo v. Hisquierdo, 439 U.S. 572 (1979) 3,10

Hodel v. Indiana, 452 U.S. 314, 323-324 (1981) 5

United States v. Steele, 147 F.3d 1316 (11th Cir. 1998)(en banc) (and cases cited therein), cert. denied, *Steele v. United States,* 528 U.S. 933 (1999).....7,8

United States v. Darby, 312 U.S. 100 (1941) 5,7

United States v. Lopez, 514 U.S. 549 (1995) 5

United States v. Moore, 423 U.S. 122 (1975).....8,9,10,14,15

United States v. Morrison, 529 U.S. 598 (2000) 5

Washington v. Glucksberg, 521 U.S. 702 (1997).....22

Ashcroft v. Oregon, (court of appeals opinion, filed May 26, 2004 -- Pet. App.).....11,14,18,20

Oregon v Ashcroft, (district court opinion and order -- Pet. App.) 8

Constitution, statutes, and regulations:

U.S. Const. Art. I, § 8, Cl. 3.....4

U.S. Const. Art. I, § 8, Cl. 18 5

U.S. Const. art. VI 3,9,24

Or. Rev. Stat. §§ 127.800 *et seq.* (2003) 7

Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996) 13

21 U.S.C. § 801 4,6

21 U.S.C. § 802 (10).....17

21 U.S.C. § 802 (21).....8,10,17

21 U.S.C. § 802 (27).....17

21 U.S.C. § 821.....15,18

21 U.S.C. § 822 (a)(2).....14

21 U.S.C. § 822 (b).....14

21 U.S.C. § 823 15,16,18,19

21 U.S.C. § 824.....14,15,18

21 U.S.C. § 829.....8,10,16,17

21 U.S.C. 830 (b)(3)(ii).....17

21 U.S.C. § 841(a) (1).....8,10

21 U.S.C. § 841 (b)(1)(C).....9,10

21 U.S.C. § 871 (b).....15

21 U.S.C. § 885(a)(1).....8

21 U.S.C. 903.....10

42 U.S.C. § 14401 et seq. 9

21 CFR § 306.04(a) (1973) (re-designated as 21 CFR § 1306.04(a) (1975).....4,8,10,11,14,17,18

Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg at 56,608) 4,11,14,18

Miscellaneous:

Sissella Bok, *Physician-Assisted Suicide*, in Euthanasia and Physician-Assisted Suicide 139 (Gerald Dworkin, et al., eds., (1998).....20

Kathleen Foley, and Herbert Hendin, The Case Against Assisted Suicide, For the Right to End-of-Life Care (Foley & Hendin, eds 2002).....12,20,21,22,23

Brief of the American Medical Assn., American Nurses Assn., American Psychiatric Assn., et al., as Amicus Curiae in Support of Petitioners at 5, *Glucksberg* (No. 96-110), available in 1996 WL 56263.....12,13

H.R. Rep. No. 1444,
91st Cong., 2d Sess. Pt. 1 (1970) 5, 7

Memorandum for the Attorney General,
(June 27, 2001 -- Pet. App.) 8,16

INTEREST OF AMICI CURIAE

This *amicus curiae* brief is filed on behalf of Focus on the Family and the Family Research Council.[1]

Focus on the Family is a non-profit religious corporation committed to strengthening the emotional, psychological, and spiritual health of children and their families in the United States and throughout the world.

Focus on the Family's Founder and Chairman, Dr. James Dobson, a distinguished child psychologist, is the author of numerous books, pamphlets, and papers on child development, education, marriage, and society. Focus on the Family and Dr. Dobson have been at the forefront of the pro-life movement and have spoken and written extensively concerning individual and societal dangers associated with assisted suicide. Focus on the Family has participated as *amicus curiae* on numerous briefs to this Court and others in cases addressing issues of life. It regularly lobbies Congress and state legislatures concerning matters associated with the sanctity and preservation of life. *See* www.family.org.

Family Research Council is a non-profit, research and educational organization dedicated to articulating and advancing a family-centered philosophy of public life. FRC is a voice for the pro-family movement in Washington, D.C., and provides policy analysis, legislative assistance, and research for pro-life and pro-family organizations. It also

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[1] In accordance with Supreme Court Rule 37(6), *amici* certify that this brief was authored entirely by Counsel of Record for *amici* and that no part of the brief was authored by any attorney for a party. The Alliance Defense Fund provided a monetary contribution to the preparation or submission of this brief; no other person or entity other than *amici curiae* or their counsel provided a monetary contribution to the preparation or submission of this brief.

seeks to educate legislators on issues that affect American families.

In addition to providing policy research and analysis for the legislative, executive, and judicial branches of the federal government, FRC works to inform the news media, the academic community, business leaders, and the general public about family issues that affect the nation. FRC publishes and disseminates resource materials, legal memoranda, and public policy studies on pro-family issues. These publications include discussions on the problems and legal controversies surrounding assisted suicide. *See* www.frc.org. Its research, publications, and films on the impact of assisted suicide have been distributed to thousands of scholars, students, organizations, and citizens. FRC's legal and public policy experts are continually sought out by members of Congress and state legislators for assistance and advice on matters of bioethics and issues relating to assisted suicide.

FRC has participated in numerous *amicus curiae* briefs in the United States Supreme Court and federal courts, including cases involving pro-life issues.

Focus on the Family and Family Research Council work to preserve and protect the family and have particular knowledge about the social and legal impact of assisted suicide that will be helpful to the Court in this case.

CONSENT TO FILE BRIEF

Petitioner and Respondents, through their counsel of record, consented to the filing of this Brief of *Amici Curiae* in support of Petitioner. Their letters of consent are on file with the Clerk of the Court.

SUMMARY OF THE ARGUMENT

The issues in this case implicate important federalism concerns vital to proper constitutional governance under the rule of law.

The appellate court's analysis, granting Oregon's request to enjoin the United States from enforcing the Federal Controlled Substances Act (CSA), is incompatible with the Supremacy Clause in Article VI of the United States Constitution. Mutually exclusive provisions of the Federal CSA and Oregon law make it impossible for a dispensing physician to comply with both. In such situations, this Court has deemed the state law preempted—even where a distinctive state interest is at stake. *See, e.g.*, *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 581 (1979) (finding state community property law preempted by federal military pay law). Thus, even *without considering* the Attorney General's reasonable interpretation of the CSA's implementing regulation, the two statutes here conflict to the extent they cannot consistently stand together.

The CSA, as interpreted by the Attorney General, does not interfere with Oregon's regulation of a traditional state function. The Oregon law authorizes and protects a non-traditional, deadly practice, using federally controlled substances—a practice condemned by the American Medical Association and our nation's leading health care provider associations. This deadly practice cannot be a traditional state function as Oregon professes it to be. As such, Oregon has no right to prevent federal enforcement of the applicable federal drug laws under the CSA.

The Attorney General's interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA, and merely verified that assisting suicide is

not a "legitimate medical purpose" within the meaning of 21 C.F.R. 1306.04. Pet. App. 100a (AG Order no. 2534-2001). When this interpretation of the CSA's implementing regulation is added into the analysis, federal preemption is irrefutable. In promulgating this interpretive rule concerning the dispensing of controlled substances, the Attorney General acted within the scope of his statutory authority.

Finally, enjoining the United States from protecting the citizenry against dispensing drugs to kill a human being creates a culture of death with serious implications.

Amici, therefore, urge this Court to reverse the decision of the United States Court of Appeals for the Ninth Circuit.

ARGUMENT

THE COURT OF APPEALS ERRED IN GRANTING OREGON'S REQUEST TO ENJOIN THE UNITED STATES FROM ENFORCING THE FEDERAL CONTROLLED SUBSTANCES ACT (CSA)[2]

The issues in this case implicate important federalism concerns vital to proper constitutional governance under the rule of law.

A. CONGRESS, PURSUANT TO ITS ENUMERATED POWERS IN ARTICLE I OF THE UNITED STATES CONSTITUTION, MAY REGULATE THE DISPENSING OF CONTROLLED SUBSTANCES BY PHYSICIANS AND OTHER MEDICAL PROFESSIONALS

Article I, of the United States Constitution, vests in Congress the power "[t]o regulate Commerce ... among the several States," U.S. Const. art. I, § 8, cl. 3. Additionally, the

[2] 21 U.S.C. §§ 801 *et seq.*

Necessary and Proper Clause, empowers Congress to enact laws reasonably necessary to carry out its power under the Commerce Clause. *Id.* at cl. 18.

This Court has held that "Congress's commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce, . . . i.e., those activities that substantially affect interstate commerce." *See United States v. Morrison*, 529 U.S. 598, 609 (2000) (quoting *United States v. Lopez*, 514 U.S. 549, 558-59 (1995)). *See also United States v. Darby*, 312 U.S. 100, 118 (1941). Congress properly exercised such Article I powers when enacting the Federal Controlled Substances Act.

Under a "rational basis" standard, broad deference is due to congressional judgments concerning whether drug dispensing activity by physicians substantially affects interstate commerce. *See Lopez, 514* U.S. at 557. Likewise, such broad deference applies to whether Congress's regulation of drugs is reasonably necessary to carry out its legislative purpose under the Commerce Clause. *Id.*[3] Here, it is clear that Congress's purpose in enacting the Controlled Substances Act was to comprehensively regulate the market of such substances. A House Report expressly stated that Congress promulgated the law in order "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States . . . through providing more effective means for law enforcement aspects of drug abuse prevention and control." H.R. Rep. No. 91-1444, Pt. 1, at 1 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

[3] "A court may invalidate legislation enacted under the Commerce Clause only if it is clear that there is no rational basis for a congressional finding that the regulated activity affects interstate commerce, or that there is no reasonable connection between the regulatory means selected and the asserted ends." *Hodel v. Indiana*, 452 U.S. 314, 323-24 (1981).

When it enacted the Federal Controlled Substances Act, Congress made the following findings and statements:

> (1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.
>
> (2) The illegal . . . distribution, and possession *and improper use* of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people. (emphasis added)
>
> (3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce . . . . 21 U.S.C. § 801.

From these and its other findings, Congress could reasonably assume that the dispensing of drugs substantially affects interstate drug commerce. It is also reasonable that federal regulation of such an activity is necessary to accomplish the congressional purpose of regulating drug commerce. Congress properly, therefore, could conclude that regulation of drug-dispensing activity is a reasonably necessary way to achieve its purpose of comprehensively regulating the interstate market in controlled substances. Including improper drug-dispensing activity for lethal purposes within the CSA's coverage furthers its legitimate objective. Indeed, excepting such activity undermines clear legislative intent to

regulate the drug market comprehensively in a manner which protects public health and safety.[4]

Moreover, no constitutional provision limits Congress from using its powers under Article I to regulate commerce in connection with medical matters. *See Darby*, 312 U.S. at 115-17 (1941) (renouncing earlier doctrines holding that Congress could not utilize the commerce power to achieve legitimate objectives relating to the health and welfare of the nation); and *see generally*, *United States v. Steele*, 147 F.3d 1316, (11th Cir. 1998) (en banc) (and cases cited therein), *cert. denied*, *Steele v. United States*, 528 U.S. 933 (1999)(upholding a conviction of a physician under the CSA for dispensing drugs outside professional limits).

B. The Federal Controlled Substances Act Preempts the Oregon Law Authorizing Doctors to Dispense Drugs to Assist Killing a Human Being

The relevant Oregon law in this case authorizes physicians, in certain circumstances, to prescribe and dispense a lethal amount of drugs for the purpose of assisting in the killing of a human being. Or. Rev. Stat. §§ 127.800 *et seq.* (2003). The Oregon law expressly provides that a physician cannot "be subject to civil or criminal liability or professional disciplinary action" for engaging in the conduct authorized by the Oregon law. *Id.* § 127.885 (1).

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[4] This is why the dispensing of controlled substances is regulated under the CSA by "provid[ing] for control . . . through registration of manufacturers, wholesalers, retailers, and all others [including physicians] in the legitimate distribution chain...." H.R. Rep. No. 91-1444, *supra*, Pt. 1, at 3, 6 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4569.

The drugs dispensed in the lethal conduct authorized by the Oregon law are controlled substances regulated under the Federal CSA. Pet. App. 114a (Memorandum for the Attorney General, June 27, 2001). Generally, such substances are among those listed in Schedule II of the CSA. *Id.; see also* Pet. App. 65a (opinion of the district court).

The conduct now authorized as legitimate and immune from prosecution under Oregon law is a prosecutable crime carrying serious penalties under the provisions of the Federal CSA.

Under the CSA, it is a federal crime for a physician to "dispense" a controlled substance without a legitimate medical purpose in the usual course of medical treatment.[5] *See* 21 U.S.C. §§ 841(a)(1), 802(21); 829; 21 C.F.R. § 306.04(a) (1973) (re-designated as 21 C.F.R. § 1306.04(a) (1975); *see also United States v. Moore,* 423 U.S. 122, 124, 139 (1975) (holding that a physician can be convicted under the CSA when acting outside professional limits).

When "death . . . results from the use of such substance" dispensed, the dispensing physician faces

[5] Whether the physician acted outside authorized professional limits is not an element of the offense that the government needs to negate; rather, it is an affirmative defense available to the practitioner who carries the burden of going forward with the evidence concerning the exception. 21 U.S.C. § 885(a)(1); *Steele*, 147 F.3d at 1318-20 (11th Cir. 1998) (en banc) (and cases cited therein). Congress clearly did not intend an exception for non-medical use of controlled substances for purposes harmful to life. There is no expression within the CSA of any such exception. Permitting states to alter the CSA by injecting such an exception holds the potential to gut the full intent of the federal law. Under the appellate court's decision, for example, California could pass a law permitting physicians to prescribe and dispense controlled substances to assist patients to get "high" in order to deal with stress.

significant penalties under the CSA. *See* 21 U.S.C. § 841 (b)(1)(C) (prescribing up to life in prison for dispensing Schedule II controlled substances in violation of § 841(a) where death results from the use of the drug); *see also Moore*, 423 U.S. at 132 (1975) (recognizing that Congress geared the CSA's penalties "to the nature of the violation, including the character of the drug involved.").

It is worth noting that Congress also expressed disapproval of physician-assisted suicide in its Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, (1997), 111 Stat. 23 (codified at 42 U.S.C. § 14401 et seq.). There, Congress expressly stated the principal purpose of the Act was "to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual." 42 U.S.C. § 14401(b). The Assisted Suicide Funding Restriction Act thus provides further confirmation that Congress, in the CSA, intended to proscribe the dispensing of controlled substances by physicians to assist in the killing of human life.

Article VI of the United States Constitution states:

> This Constitution, and *the Laws of the United States* which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the . . . laws of any State to the Contrary notwithstanding. U.S. Const. art. VI (emphasis added).

The Federal CSA expressly preempts state laws to the extent "there is a positive conflict between [a provision

of the CSA] and that state law so that the two cannot consistently stand together." 21 U.S.C. § 903. To be sure, nothing in the CSA prevents a state from enacting its own stricter drug legislation, or prosecuting drug offenses at the state level. *Id.* And, nothing in the Federal CSA preempts a state from regulating within the field of physician-assisted suicide (i.e., nothing in the CSA preempts a state law authorizing physician assisted suicide *per se*).

Under conventional conflict preemption principles, however, the Federal CSA clearly preempts Oregon's statute authorizing *the dispensing of controlled substances* to assist suicide. The CSA proscribes the dispensing of controlled substances by physicians without a legitimate medical purpose in the usual course of medical treatment—and provides severe penalties when "death . . . results from the use of such substance . . . ." *See* §§ 841(a)(1), 802(21), 829; 21 C.F.R. § 1306.04(a) (1975); *Moore*, 423 U.S. at 124 (1975); and 21 U.S.C. § 841 (b)(1)(C). Oregon's law, on the other hand, expressly authorizes—and immunizes against prosecution—the lethal dispensing proscribed and severely penalized by the CSA. Thus, the two statutes here conflict to such an extent that they cannot consistently stand together.

Moreover, even if the CSA did not expressly preempt the Oregon statute, implied preemption exists where "compliance with both federal and state regulations is a physical impossibility." *Boggs v. Boggs*, 520 U.S. 833, 844 (1997) (internal quotation marks omitted) (citing *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)). The mutually exclusive provisions of the CSA and Oregon law governing the dispensing of controlled substances make it impossible for a dispensing physician to comply with both. In such situations, this Court has deemed the state law preempted—even where a distinctive state interest is at stake. *See, e.g., Hisquierdo v. Hisquierdo*, 439 U.S. 572,

581 (1979) (finding state community property law preempted by federal military pay law).

Thus, the Ninth Circuit's analysis, granting Oregon's request to enjoin the United States from enforcing the Federal CSA, is incompatible with the Supremacy Clause in Article VI of the United States Constitution. The CSA and its implementing regulations plainly proscribe, and therefore preempt, Oregon's law authorizing the dispensing of drugs to assist in the death of a human being—even *without considering* the Attorney General's statutorily authorized reasonable interpretation of the CSA's implementing regulation at issue here. As discussed in more detail in section D of this brief, this interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 1306.04. Pet. App. 100a (AG Order no. 2534-2001). When this reasonable interpretation of the CSA's implementing regulation is added into the analysis, the certainty of federal preemption is irrefutable.

At bottom, the Ninth Circuit's analysis incorrectly presumes this case is about Oregon's right to regulate the practice of medicine—suggesting that the Attorney General's ruling alters the usual constitutional balance between the states and federal government. Pet. App. at 11a (court of appeals opinion). The problem with the appellate court's federalism analysis is that it analyzes oranges when this case is about apples. This case is not about the regulation of medical practice; it is about the right of the federal government to regulate controlled substances in a uniform manner.[6]

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[6] We also note that the appellate court over-states Oregon's situation, given that Oregon stands alone among the fifty states in having radically departed from accepted medical practice. Physician-assisted suicide bills

C. Dispensing Controlled Substances to Assist Suicide Is Not a Traditional State Medical Practice Protected from Federal Regulation

The CSA, as interpreted by the Attorney General, does not interfere with Oregon's regulation of a traditional state function. Nothing in the record suggests that dispensing drugs to assist suicide is a traditional or legitimate medical practice subject to state regulation. As such, Oregon has no peculiar local, historical, or traditional interest in its regulation. It certainly, therefore, has no right to prevent federal enforcement of the federal drug laws under the CSA.

The Hippocratic Oath, written during the fifth to fourth centuries B.C., declares, "I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect." In keeping with that fundamental principle of medicine, the AMA and more than 40 other national and state medical and health care organizations have urged on this Court that "the ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics. . . ." Brief of the American Medical Ass'n, American Nurses Ass'n, American Psychiatric Ass'n, et al., as Amicus Curiae in Support of Petitioners at 5, *Glucksberg* (No. 96-110), *available at* 1996 WL 656263.

The AMA has "reexamined and reaffirmed" that "physician-assisted suicide remains 'fundamentally incompatible with the physician's role as healer, would be

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in more than 20 states have failed in the past decade, whereas 16 bills prohibiting it have been enacted in the past decade and a half. Yale Kamisar, *The Rise and Fall of the "Right" to Assisted Suicide*, in Foley & Hendin, eds., *The Case Against Assisted Suicide, For the Right to End-of-Life Care* 91 (2002) (citations omitted).

difficult or impossible to control, and would pose serious societal risks.'" *Id.* Thus, in reality, the Oregon law authorizes and protects a non-traditional, deadly practice using federally controlled substances. Such a practice cannot be considered medicine (traditionally regulated as a state function) as Oregon professes it to be. Thus, if suicide is not medicine, Oregon cannot, in its authorization of the use of federally controlled substances to assist suicide, claim to be regulating medicine as a traditional state function. Assisted-suicide law cannot be regulating medicine as a traditional state function.

Moreover, relatively few instances even exist in which Oregon has invoked its state law. These few instances hardly suggest a significant local impact. Certainly no widespread impact on the practice of medicine in Oregon exists from the Attorney General's interpretation of the CSA. Up until the time when Oregon passed its law, the practice of medicine in Oregon (and in every other state) did not involve assisting suicide using federally controlled substances. Oregon's federalism argument is, therefore, a canard where the federal regulation has no direct effect on truly traditional state medical practice.

To be sure, Oregon can regulate whether its physicians must be licensed. Oregon can also provide that physicians must keep their patients' records confidential—though even that duty is the subject of federal standards. *See* Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996). Oregon's attempt to legitimize the misuse of federally controlled substances to take human life (and to provide immunity to physicians violating federal regulations prohibiting that misuse), however, cannot stand.

D. THE ATTORNEY GENERAL ACTED WITHIN HIS STATUTORY AUTHORITY

The court of appeals erred when it held that the interpretive rule promulgated by the Attorney General fell outside his statutory authority. Pet. App. 9a (court of appeals opinion).

As previously discussed, the Attorney General's interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA. It also verified that helping one to kill oneself is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 1306.04. Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg at 56,608). The interpretive rule further concluded that "[s]uch conduct by a physician registered to dispense controlled substances *may* 'render his registration . . . inconsistent with the public interest' and therefore subject to *possible* suspension or revocation." *Id.* (quoting 21 U.S.C. § 824(a)(4)) (emphasis added). For the reasons discussed below, the Attorney General acted within his statutory authority when he promulgated this interpretive rule.

Congress, through the CSA, used the concept of "registration" to identify those physicians who operate "beyond the bounds of professional practice." *Moore*, 423 U.S. at 139 (1975). Physicians and others, who dispense a controlled substance, must "obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him." 21 U.S.C. § 822 (a)(2). Under the CSA, physicians and others registered by the Attorney General to dispense controlled substances are authorized to dispense such substances only "to the extent authorized by their registration and in conformity with the [provisions of the CSA]." 21 U.S.C. § 822 (b). Thus, only

"the lawful acts of registrants are exempted" from prosecution. *Moore*, 423 U.S. at 130 (1975).

Congress expressly granted the Attorney General the authority "to promulgate rules and regulations . . . relating to the registration and control of the . . . dispensing of controlled substances and to the registration and control of regulated persons and regulated transactions." 21 U.S.C. § 821.[7]

Under 21 U.S.C. § 823(f), Congress gave the Attorney General the express authority to deny an application for registration "if he determines the issuance of such registration is inconsistent with the public interest." Moreover, Congress also expressly gave the Attorney General the authority to suspend or revoke a registration authorized pursuant to section 823 if the Attorney General finds that the registrant committed an act that would "render his registration under section 823 [of the CSA] inconsistent with the public interest as determined under such section." 21 U.S.C. § 824.

In denying, revoking, or suspending an application, the Attorney General must consider the following factors in determining the public interest:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

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[7] Congress expressly further granted the Attorney General the authority to "promulgate and enforce any rules, regulations, and procedures" deemed "necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b).

(2) The applicant's experience dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823.

Most of the drugs dispensed in the lethal conduct authorized by the Oregon law likely fall within Schedule II of the CSA, the "most strictly regulated category of substances available for non-research purposes." Pet. App. 114a (Memorandum for the Attorney General, June 27, 2001). *See also* Pet. App. 65a (opinion of the district court).

In 21 U.S.C. § 829, Congress mandated the following in connection with the dispensing of Schedule II controlled substances:

> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II . . . may be dispensed without the written prescription of a practitioner, [with emergency exceptions not relevant to the discussion at bar]."[8]

[8] The word "dispense" means "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . . ." 21 U.S.C. § 802(10). "'Ultimate user' means a person who has lawfully obtained ... a controlled substance for his own use . . . ." 21 U.S.C. § 802 (27). The term "practitioner" includes a "physician . . . licensed, *registered*, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . [to] dispense . . . a controlled substance in the course of professional practice . . . ." 21 U.S.C. § 802 (21) (emphasis added).

Pursuant to the above discussed rulemaking authority vested in the Attorney General by Congress, the Attorney General, in the early 1970's, enacted regulations pursuant to Section 829:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning of this Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provide for violations of the provisions of law relating to controlled substances.

21 CFR § 306.04(a) (1973) (redesignated as 21 C.F.R. § 1306.04(a) (1975).[9]

If the Attorney General in the early 1970's promulgated the above rule pursuant to statutory authority,

[9] *See also*, 21 U.S.C. § 830 (b)(3)(ii) *Regulation of Llisted Chemicals –l Mail Order Reporting* – "The term 'valid prescription' means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to . . . prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice."

then the Attorney General in 2001 certainly had the authority to interpret what it means. Indeed, as noted above, Congress, in 21 U.S.C. § 821, expressly granted the Attorney General authority "to promulgate rules and regulations . . . relating to the registrations and control of the . . . dispensing of controlled substances and to the registration and control of regulated persons and regulated transactions." The Attorney General's interpretive ruling directly promotes the CSA's purposes, by restricting use of controlled substances to legitimate medical purposes. It promotes the medical use of drugs, furthering the public interest in a manner perfectly consistent with the broad intent of Congress. Thus, when the Attorney General published the interpretive rule, confirming that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. 1306.04, he acted well within his congressionally authorized authority. Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg. at 56,608).

Moreover, it was reasonable for the Attorney General to subsequently conclude in the interpretive rule that "[s]uch conduct by a physician registered to dispense controlled substances *may* 'render his registration . . . inconsistent with the public interest' and therefore subject to *possible* suspension or revocation." Pet. App. 100a (AG Order no. 2534-2001, 66 Fed. Reg. at 56,608 (quoting 21 U.S.C. § 824(a)(4))) (emphasis added).

The court of appeal's holding that the Attorney General's action exceeded statutory authority because it "evaluates public interest under 21 U.S.C. § 823 without considering all five factors required by that subsection" is misplaced. Pet. App. 17a (court of appeals opinion).

This part of the Attorney General's interpretive rule is merely public notice of a logical consequence that *may* come to one from ignoring the previously established premise that dispensing drugs to assist one to kill oneself is not a legitimate medical practice and violates the CSA. In this regard, although the Attorney General certainly evaluated the public's interest in promulgating the interpretive rule, nothing in the law requires him to consider all five factors delineated in 21 U.S.C. § 823(f). Under the CSA, the Attorney General is required to consider these five factors only when denying, revoking, or suspending an application for a registration. 21 U.S.C. §§ 823(f), 824. Nothing in the record indicates that the Attorney General has even contemplated taking such action against the named plaintiffs. Thus, the court of appeals erred since no statutory authority required the Attorney General to consider the five factors when promulgating the interpretive rule.

E. Enjoining the United States from Protecting the Citizenry against Dispensing Drugs to Kill a Person, Creates a Culture of Death with Serious Implications

The court of appeals mandated that the United States must not enforce the nation's drug laws against physicians who dispense controlled substances to assist in the killing of a human being. *Amici* believe that human beings are made in the image of God and that, therefore, every life is sacred. *Genesis* 1:26. Underlying the court of appeals decision is a rejection of this inviolable standard present in the natural law, divine law, and positive law, in favor of a morally-relative standard where each individual chooses when and whether a human life has value.

Ultimately, allowing the dispensing of federally controlled drugs to assist suicide flows directly from the

fundamentally erroneous premise that human life in certain conditions has no positive value. That premise has incalculably serious implications for all of us. Here, an appellate court has ruled that individuals have the right to take life in certain situations, and that the United States cannot enforce the federal drug laws in ways that protect life. When we abandon moral absolutes today, it becomes easy tomorrow to choose death in other ways, for other people, in other situations, since the positive value of life has become an immorally-relative individual choice.

The prominent ethicist Sissela Bok concluded, "No society has yet worked out the hardest questions of how to help those patients who desire to die, without endangering others who do not." Sissella Bok, *Physician-Assisted Suicide*, in *Euthanasia and Physician-Assisted Suicide* 139 (Gerald Dworkin, et al., eds., (1998)).

Prior to the enactment of the Federal CSA,[10] euthanasia societies grew during the late 19th and early 20th century eugenics movements in the United States and Europe. Kathleen Foley and Herbert Hendin, *Introduction*, in *The Case Against Assisted Suicide, For the Right to End-of-Life Care* 6-7 (Foley & Hendin eds., 2002). Thirty states passed sterilization laws embraced by both Presidents Theodore Roosevelt and Woodrow Wilson. *Id.*

The Nazis legalized voluntary euthanasia, and then involuntarily euthanized hundreds of thousands of the mentally ill; they then extended euthanasia's reach to Jews, gypsies, and other "undesirables." *Id.* at 7.

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[10] The Ninth Circuit erred in relying on former Attorney General Reno's January 5, 1998 letter suggesting that the CSA did not prohibit prescription-assisted suicide. *See* Pet. App. 7a. The Reno letter assumed, ahistorically, that the CSA was written before there was any consideration of assisted suicide.

As late as the 1940s, this country's leading euthanasia proponent, Dr. Foster Kennedy, continued to advocate compulsory euthanasia for retarded children on eugenics grounds. By the 1970s, the euthanasia movement's focus shifted to easing the "burden" of caring for the elderly, and then to easing suffering, *id.* at 8,—though notably, no suffering requirement exists in the Oregon law, which purports instead to be based on personal choice. The Oregon law requires the physician to advise the patient of palliative care and hospice, but does not require that the physician have any training in either and requires no palliative care consultation.

While utterly failing to protect the family of the patient, the Oregon law grants "good faith" immunity to the physician and fails to provide an enforcement mechanism for physician non-compliance. Moreover, inadequate data collection requirements limit any possible study of the Oregon experiment. For example, the form used by Oregon to effectuate the killing requires no disclosure of the reason for the patient's request. *Id.*

The Dutch experiment in physician-assisted suicide failed frighteningly. Dutch legal requirements were consistently violated and could not be enforced. *Id.* at 10. Sixty percent of Dutch assisted suicide cases go unreported. *Id.* Most non-reporting involves cases in which physicians failed to follow established guidelines for voluntariness or consultation.

Worse, in several thousand cases each year physicians ended their patient's life without the patient's consent. *Id.* Twenty-five percent of physicians terminated one or more patient's life without request. *Id.* In the 1995 study year, 40 percent of the more than 6,000 cases in which

physicians actively intervened to cause death involved no explicit request from the patient. Herbert Hendin, *The Dutch Experience*, in Foley & Hendin, *supra*, at 105; *see also* Zbigniew Zylicz, M.D., *Palliative Care and Euthanasia in the Netherlands: Observations of a Dutch Physician*, in Foley & Hendin, *supra*, at 123.

Each major Dutch measure enacted to control and regulate physician-assisted suicide (including informed consent, consultation, and reporting) largely failed, was modified, or was violated. Foley & Hendin, *supra*, at 103 (citing C. Gomez, *Regulating Death: Euthanasia and the Case of the Netherlands* (1991)). This Court in *Washington v. Glucksberg*, 521 U.S. 702, 733 (1997), recognized that "what is couched as a limited right to 'physician-assisted suicide' is likely, in effect, a much broader license, which could prove extremely difficult to solve and contain." Indeed, what we sow today, we will reap tomorrow.

As the fundamental units of society, families must be protected and promoted by the law and by legal institutions, if order and liberty are to flourish. Yet clinical research shows that suicides in general and physician-assisted suicides more particularly, devastate families. M.D. Reed and J.Y. Greenwald, *Survivor Victim Status, Attachment and Sudden Death Bereavement*, 21 J. of Suicide and Life-Threatening Behavior 385-401 (1991); N.L. Farberow, D.E. Gallagher-Thompson, N.J. Gilewski, and L.W. Thompson, *Changes in Grief and Mental Health of Bereaved Spouses of Older Suicides*, 47 J. Gerontology 357-66 (1992), both cited in Kathleen Foley and Herbert Hendin, *The Oregon Experiment*, in *The Case Against Assisted Suicide, For the Right to End-of-Life Care* 158 (Foley & Hendin, ed. 2002) (noting the "devastating grief and guilt that we see in survivors of suicide").

Imagine the shock of an adult child making the weekly visit to a parent's nursing home, only to discover that a physician proscribed and dispensed a federally controlled substance to help the parent commit suicide the day before. (Oregon's law requires no pre-suicide notification to families.)

The toll on family life is incalculable. Allowing physicians to dispense drugs to assist in killing has an insidious effect on families who support seniors, burdening both the family and the dying. The number of patients in Oregon reporting a concern about being a burden on the family increased from 12 percent in 1998 to 63 percent in 2000, subsequent to the passage of Oregon's physician-assisted suicide law. *Id.* at 162. Physician-assisted suicide creates in practice a frightening "duty to die"—frightening because the practice of physician-assisted suicide has been shown to be so imperfect a means of death that in one Dutch study fully 20 percent of patients given what was considered to be a lethal dose lived for more than three hours, in some cases requiring the physician to intervene with a lethal injection which would be illegal under the Oregon law. *Id.* at 166 (citing J.H. Groenewould, A. van der Heide, B.D. Onwuteaka-Philipsen, D.L. Willems, P.J. van der Maas, and G. van der Wal, *Clinical Problems with the Performance of Euthanasia and Physician-Assisted Suicide in the Netherlands*, 342 New England J. Med. 551-56 (2000). Families are occasionally called on to intervene with pillows or plastic bags. Foley & Hendin, *supra* at 164 (citations omitted).

The court of appeals decision rejects the inviolable standard serving as the foundation for the Hippocratic Oath, as well as the AMA's view that physician-assisted suicide is fundamentally incompatible with the physician's role as healer. Underlying its decision instead is a morally-relative

foundation, where each individual chooses when and whether a human life has positive value. The serious implications for our nation that accompany such a choice are clear. Proper historical foundations do matter. Because they do, *amici* urge this Court to reverse the decision of the court of appeals.

CONCLUSION

This case implicates important federalism concerns vital to proper constitutional governance under the rule of law. Mutually exclusive provisions of the Federal CSA and Oregon law make it impossible for a dispensing physician to comply with both laws. Thus, the Federal CSA preempts the Oregon law. The appellate court's analysis, granting Oregon's request to enjoin the United States from enforcing the Federal CSA, is incompatible with the Supremacy Clause in Article VI of the United States Constitution.

The Attorney General's interpretive rule confirmed that dispensing controlled substances to assist suicide violates the CSA, and verified that assisting suicide is not a "legitimate medical purpose." The Attorney General, in promulgating this rule, acted well within a plethora of statutory authority expressly allowing him to do so.

Amici ask that this Court restore the right of the federal government to enforce our nation's drug laws under the CSA. Undeniably, we stand at a statutory construction site. If, in the name of an individual's morally relative choice, we enjoin the federal government from proscribing the dispensing of drugs to kill a human being, we merely create an illusion of a nation willing to protect fundamental freedoms. Such a course inevitably erodes the fundamental foundations of our country. As structural institutions of free

government stand for a time, the essence for which they stand ceases to exist. Who we are morally, as a nation, matters. Those who came before us built a constitutional, democratic republic upon fundamental foundations of decency. It is now our watch. It is well for us to recall, therefore, the ancient truth that "righteousness exalts a nation." *Proverbs* 14:34.

For the reasons discussed, *amici* urge this Court to reverse the United States Court of Appeals for the Ninth Circuit.

Respectfully submitted,

WILLIAM WAGNER
NELSON P. MILLER
Counsel of Record

STEPHEN W. REED
35 N. Lake Ave.
Pasadena, CA 91101
(626)449-4521

COOLEY LAW SCHOOL
300 South Capitol
Lansing, MI 48933
(517) 371-5140

PATRICK A. TRUEMAN
801 G. Street NW
Washington D.C. 2001
(202)393-2100

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No. 04-623

IN THE

Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, et al.,
Petitioners.
v.

STATE OF OREGON, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

BRIEF FOR AMICUS CURIAE LIBERTY COUNSEL IN SUPPORT OF PETITIONERS

Mathew D. Staver
(Counsel of Record)
Erik W. Stanley
Anita L. Staver
Rena M. Lindevaldsen
Mary E. McAlister

LIBERTY COUNSEL
210 East Palmetto Avenue
Longwood, FL 32750
(407) 875-2100
Attorneys for Amicus Curiae

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801, *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

TABLE OF CONTENTS

QUESTION PRESENTED i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES v

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT 1

ARGUMENT 3

I.

THE ATTORNEY GENERAL HAS PROPERLY EXERCISED HIS ROLE AS PROTECTOR OF THE INALIENABLE RIGHT TO LIFE. 3

A. The Inalienable Right To Life Has Been Recognized And Protected Since Before The Birth Of This Nation 3

B. The Attorney General Has Properly Stepped In To Protect The Right To Life From Threatened Extinction By The Oregon Assisted Suicide Law 5

C. The Attorney General Has Restored Inalienability Of The Right To Life For Terminally Ill Patients 7

II.

THE ATTORNEY GENERAL HAS ACTED PROPERLY TO PROTECT THIS COURT'S PRECEDENTS UPHOLDING THE GOVERNMENT'S INTEREST IN THE PRESERVATION OF LIFE 9

A. The Attorney General Has Upheld The Government's Unqualified Interest In Preservation Of The Right To Life Addressed In *Washington v. Glucksberg* 10

B. The Attorney General Has Properly Refused To Apply The "Quality Of Life" Analysis Rejected in *Cruzan v. Director* 11

C. The Attorney General Has Protected The Most Vulnerable Citizens From Degradation Of Their Right To Life As Provided in *Vacco v. Quill.* 12

III.

THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA PRESERVES MORE THAN A CENTURY OF STATE PROTECTION OF THE INALIENABLE RIGHT TO LIFE.. 13

IV.

THE ATTORNEY GENERAL'S

INTERPRETATION OF THE CSA PROPERLY PROTECTS THE INTEGRITY OF THE MEDICAL PROFESSION AND ITS COMMITMENT TO HEALING AND THE PRESERVATION OF LIFE 18

CONCLUSION 19

TABLE OF AUTHORITIES

CASES **Page(s)**

Blackburn v. State,
23 Ohio St. 146, 163 (1872) 13, 14

Cruzan v. Director, Missouri Department of Health,
497 U.S. 261 (1990) 2, 6-8, 11, 15

Donaldson v. Lungren,
2 Cal. App. 4th 1614, 1624 (1992) 15

In re Caulk,
125 N.H. 226, 232 (1984) 17

In re Joseph G.,
34 Cal.3d 429, 435 (1983) 15

In re L.W.,
167 Wis. 2d 53, 90 (1992) 16

Martin v. Commonwealth,
184 Va.1009, 1018-1019 (1946) 13

Matter of O'Connor,
72 N.Y.2d 517, 530 (1988) 17

McKay v. Bergstedt,
106 Nev. 808, 816 (1990) 16, 19

Montalvo v. Borkovec,
256 Wis. 2d 472, 488 (Wis. App. 2002) 16

People v. Roberts,
211 Mich. 187, 196 (1920) 14, 15

People v. Kevorkian,
447 Mich. 436 (1994) 14

Ponzi v. Fessenden,
258 U.S. 254, 262 (1922) 6

Sampson v. State,
31 P.3d 88, 89 (Alaska 2001) 16

Vacco v. Quill,
521 U.S. 793 (1997) 2, 12

Washington v. Glucksberg,
521 U.S. 702 (1997) 2, 7, 10, 11, 18, 19

STATUTES **Page(s)**

21 U.S.C. §801, *et seq.* i

OTHER AUTHORITIES **Page(s)**

American Medical Association,
Code of Medical Ethics, §2.211 ..... 18, 19

AMA letter in support of H.R. 1003,
143 CONG REC. S3249-01 (April 15, 1997) 18

Avila, *Assisted Suicide and the Inalienable Right to Life*,
16 ISSUES L. & MED. 111, 112 (2000) 3, 4, 8, 9

Bopp and Avila, *The Due Process 'Right to Life' in Cruzan and Its Impact on 'Right-to-Die' Law,"*
53 U. PITT. L. REV. 193, 210 (1991) 6

Brief for the American Medical Association ,
Washington v. Glucksberg, 521 U.S. 702 (1997) . 18

Comment and Note, *Vacco v. Quill and the Inalienable Right to Life*,
11 REGENT L. REV. 373, 391 (1999) 6, 8

John Locke, Second Treatise on Government: An Essay Concerning the True Origin, Extent, and End of Civil Government §6,
J. LOCKE, TWO TREATISES OF GOVERNMENT 117 (M. Goldie ed., Everyman Library 1993) (1690). 4

The Declaration of Independence, para.2 (U.S. 1776) 3

Torzilli, *Reconciling the Sanctity of Human Life, The Declaration of Independence, and the Constitution*,
40 CATH. LAW. 197, 215-216 (2000) 4, 5

INTEREST OF AMICUS CURIAE[1]

Liberty Counsel is a non-profit civil liberties education and legal defense organization devoted to preserving religious liberty, the sanctity of human life and traditional families. Liberty Counsel has worked on legislation, public policy and litigation throughout the country as part of its mission to ensure that the Founding Fathers' commitment to the inalienable right to life remains firmly ensconced in our cultural foundation. The issues raised in the present action are critical to the continued preservation of the inalienable right to life in this country, and must be given thorough and thoughtful consideration by this Court. Liberty Counsel is concerned that the issue of the sanctity of human life not be overlooked in the Court's analysis and respectfully submits this brief to assist the Court in its examination of that issue.

SUMMARY OF ARGUMENT

This case is not merely about states' rights or regulation of the practice of medicine, but something far more fundamental and far more consequential – protection of the sanctity of life of the nation's most vulnerable and fragile citizens. Oregon's Death with Dignity Act threatens more

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[1] Liberty Counsel files this brief with the consent of all parties. The letters granting consent of the parties are attached hereto with the filing of this brief. Counsel for a party did not author this brief in whole or in part. No person or entity, other than *Amicus Curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

than 200 years of constitutional, statutory and regulatory protection of the inalienable right to life. By interpreting the Controlled Substances Act ("CSA") to prohibit physicians from prescribing controlled substances for assisted suicide, the Attorney General has acted to shore up the sanctity of human life from the damage done by Oregon's assisted suicide law.

The Attorney General's determination that the prescription of controlled substances for assisted suicide is not a legitimate medical purpose under the CSA helps protect the inalienable right to life, one of the founding principles of the nation. Oregon's Death with Dignity Act undermines this Court's commitment to the sanctity of human life as expressed in *Washington v. Glucksberg*, 521 U.S. 702 (1997), *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990) and *Vacco v. Quill*, 521 U.S. 793 (1997). The Attorney General has helped re-strengthen those precedents by preventing the prescription of controlled substances to assist in terminating life.

The Attorney General's actions also preserve more than a century of state court precedents upholding the inalienable right to life. Numerous states have repeatedly upheld the right against attempts such as Oregon's to develop qualified rights based upon purported evaluations of the "quality of life."

Most importantly, Petitioner's actions manifest a proper exercise of the Government's duty to secure the right to life for all citizens of this country, and most especially those who are suffering from disabilities or chronic or terminal illnesses.

ARGUMENT

I. THE ATTORNEY GENERAL HAS PROPERLY EXERCISED HIS ROLE AS PROTECTOR OF THE INALIENABLE RIGHT TO LIFE.

A. The Inalienable Right To Life Has Been Recognized And Protected Since Before The Birth Of This Nation.

> We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness. That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed...

The Declaration of Independence, para.2 (U.S. 1776).[2]

As these words penned by the Founding Fathers attest, "We have built our system of government on the platform of fundamental rights by regarding them as inalienable possessions of all persons." Avila, *Assisted Suicide and the Inalienable Right to Life*, 16 ISSUES L. & MED. 111, 112 (2000) ("*Assisted Suicide*"). "Many persons have come to rely

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[2] In addition, the constitutions of at least twenty-three states "refer expressly to the 'unalienable' or 'inalienable' right to life." *See* Avila, *Assisted Suicide and the Inalienable Right to Life*, 16 ISSUES L. & MED. 111, 141 n.6 ("*Assisted Suicide*").

on the security provided by the status of being regarded by the government as possessing an inalienable right to the protection of life." *Id.* at 112-113.

The concept of an inalienable right to life arose from writers such as John Locke, who "asserted that each individual owed a duty to God to preserve his or her life." *Id.* at 114.[3] "Accordingly, individuals obliged by divine sanction to protect their lives neither held the power to license other individuals to imperil their lives nor possessed the authority to release the sovereign from its corresponding duty to defend their lives." *Id.* "Any supposed freedom to consent to the interference with one's own life would conflict with one's personal duty before God and therefore constitute a nullity." *Id.* "Thus a government could not usurp this property interest under the guise of a social compact." *Id.* This promise that "the law will regard all lives as inalienable, associating these lives with a particular level of protection and status, weaves itself in and through" the history of our founding. *Id.* at 118.

This is borne out not only in the explicit declaration of the inalienable right to life in the Declaration of Independence, but also in the Constitution, which "established a governmental system best suited to secure the rights embraced by the Declaration of Independence,"especially the most fundamental of these rights – the right to life. Torzilli, *Reconciling the Sanctity of Human Life, The Declaration of Independence, and the Constitution,* 40 CATH. LAW. 197, 215-216 (2000). Therefore, while the founders first

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[3] Citing John Locke, Second Treatise on Government: An Essay Concerning the True Origin, Extent, and End of Civil Government §6, in J. LOCKE, TWO TREATISES OF GOVERNMENT 117 (M. Goldie ed., Everyman Library 1993) (1690).

enunciated the right to life, liberty and the pursuit of happiness in the Declaration of Independence, they established the means to protect those "natural human rights from governmental curtailment" through the Constitution and Bill of Rights. *See id.*

Therefore, the government's obligation to uphold the Constitution of the United States means that it is obligated to protect the inalienable right to life for all citizens without regard for issues such as the "quality of life." Oregon has disregarded its obligation and declared that the inalienable right to life does not apply to terminally ill patients. The Attorney General responded properly to this derogation of duty by ensuring that physicians would not be permitted to participate by prescribing controlled substances.

B. The Attorney General Has Properly Stepped In To Protect The Right To Life From Threatened Extinction By The Oregon Assisted Suicide Law.

> If an individual disregards the duty he owes to his Creator to continue living, the duty still remains. Since the duty persists, so does the right. The right is inalienable. In other words, a person who no longer wishes to continue living and consents to another's deadly actions still has the duty and therefore the right to continue living. This right remains and continues to protect the individual from the harmful actions of others even when the individual no longer wishes to be protected. A government that seeks to secure inalienble rights must prohibit and punish such harmful

> actions even when the individual would consent to them.

Comment and Note, *Vacco v. Quill and the Inalienable Right to Life*, 11 REGENT L. REV. 373, 391 (1999) ("Comment"). "Since life is the right to have rights, all other rights are contingent and secondary. Death is not even a secondary right; it is the extinction of rights." Bopp and Avila, *The Due Process 'Right to Life' in Cruzan and Its Impact on 'Right-to-Die' Law,"* 53 U. PITT. L. REV. 193, 210 (1991) ("*Right to Life*").

By legalizing assisted suicide, Oregon has abrogated its duty to protect the right to life for all of its citizens under the guise of a protecting a social compact with a particular segment of the population. Neither that segment of the population nor any other group has the authority to release the state from its duty to defend the inalienable right to life. Oregon has sanctioned the extinction of the most fundamental human right and abrogated its duty to prohibit and punish the actions of those who want to deprive citizens of their right to life. The state is obligated to regard ALL lives as inalienable – not merely those lives deemed to be of sufficient "quality."

Since Oregon failed to fulfill its obligations to protect the right to life for all Oregonians, the Attorney General acted properly by stepping in to restore the promise left meaningless by adoption of the Death with Dignity Act. As the "hand of the president in taking care that the laws of the United States in protection of the interests of the United States in legal proceedings and in the prosecution of offenses be faithfully executed,"[4] the Attorney General must ensure that the

[4] *Ponzi v. Fessenden*, 258 U.S. 254, 262 (1922).

inalienable right to life is secured for all citizens and protected against government abridgement. By interpreting the CSA to prohibit the prescription of controlled substances for assisted suicide, the Attorney General has protected the right to life from the government truncation and degradation inherent in Oregon's Death with Dignity Act. By utilizing his power to regulate physician prescriptions under the CSA, the Attorney General did what Oregon failed to do by prohibiting actions that would harm the fundamental right to life. The Attorney General's ruling prohibiting prescriptions of controlled substances to assist in suicide is a proper exercise of his obligation to secure the inalienable rights of the citizens of the United States.

C. The Attorney General Has Restored Inalienability Of The Right To Life For Terminally Ill Patients.

As one commentator eloquently stated:

> A law such as the Oregon Death with Dignity Act declares those deemed eligible for suicide assistance to be outside the criminal and civil codes' full protection, thereby reneging on a fundamental promise first expressed in the Declaration of Independence. No longer are all lives regarded as inalienable. Far from constituting a harmless action no more detrimental than technical trespass, the legalization of suicide assistance strikes at the heart of the relationship between the government and the individual by qualifying the law's full protection against killing

> according to one's physical qualities and proximity to death, thereby interfering with the status of being regarded as having an inalienable right to the protection of life.

Assisted Suicide at 129. Oregon has attempted to alienate what is inalienable under the guise of granting more autonomy to its citizens to choose their time and method of death. What Oregon has failed to acknowledge, however, is that "[w]here civil government exists to secure inalienable rights, the autonomy of individuals necessarily will be constrained." Comment, at 392. Under a pure system of personal autonomy, a person would be free to kill another if the killer and victim both agreed. *Id.* However, when "it is acknowledged that individuals possess inalienable rights and government exists to secure these rights, a man does not have this freedom." *Id.* "One man may not kill another, even on request, because every man has an inalienable right to life." *Id.* "No man can get away from the right; it exists as long as he lives. It is a part of his very essence." *Id.* at 393 (citing *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 295 (1990) (Scalia, J., concurring)). "Although civil government should not interfere with an individual's fulfillment of, or failure to fulfill, his duty to live, it should proscribe the actions of others that violated the inalienable right to life that flows from that duty." Comment at 393. That is what the Attorney General has done in this case.

By permitting terminally ill patients to request help in committing suicide, Oregon has deprived an entire class of people of their inalienable right to life. *See Assisted Suicide*, at 136. Oregon has told an entire segment of its population that they are no longer worthy to be endowed with an inalienable right to life. At a time when someone has been

diagnosed as terminally ill and most needs safeguarding, the state is telling him that he now has less protection in his inalienable right to life. What would otherwise be a crime – depriving someone of his inalienable right to life – can be disregarded so long as law enforcement is satisfied that the vulnerable, terminally ill patient has "consented," either directly or indirectly through a surrogate decisionmaker. *See id.* The state argues that assisted suicide is only an option and therefore does not lessen the value of life. However, the mere act of providing an option communicates to terminally ill patients that what was an inalienable right has become alienable.

The Attorney General's interpretation of the CSA to prohibit controlled substance prescriptions for assisted suicide helps restore the inalienable right to life to terminally ill patients in Oregon and ensures that right will be protected for other citizens who might face similar laws in the future. Far from overstepping his bounds, the Attorney General has acted responsibly to preserve and protect the sanctity of human life.

II. THE ATTORNEY GENERAL HAS ACTED PROPERLY TO PROTECT THIS COURT'S PRECEDENTS UPHOLDING THE GOVERNMENT'S INTEREST IN THE PRESERVATION OF LIFE.

By concluding that physicians cannot prescribe controlled substances for the purpose of assisting suicide, the Attorney General has properly carried out his duty to uphold this Court's precedents that affirm the government's pre-eminent interest in protecting the inalienable right to life.

A. The Attorney General Has Upheld The Government's Unqualified Interest In Preservation Of The Right To Life Addressed In *Washington v. Glucksberg.*

Referencing the Model Penal Code's prohibition against aiding suicide, this Court echoed the code drafter's observation that "the interest in the sanctity of life that are represented by the criminal homicide laws are threatened by one who expresses a willingness to participate in taking the life of another even though the act may be accomplished with the consent, or at the request of the suicide victim." *Washington v. Glucksberg,* 521 U.S. 702, 716 (1997). "Washington has an unqualified interest in the preservation of human life. The State's prohibition on assisted suicide, like all homicide laws, both reflects and advances its commitment to this interest." *Id.* at 728. The state "has an interest in protection of vulnerable groups – including the poor, the elderly, and disabled persons – from abuse, neglect, and mistakes." *Id.* at 731. "The State's assisted-suicide ban reflects and reinforces its policy that the lives of the terminally ill, disabled, and elderly people must be no less valued than the lives of the young and healthy, and that a seriously disabled person's suicidal impulses should be interpreted and treated the same way as anyone else's." *Id.* at 732.

By contrast, Oregon's assisted suicide law reflects a policy that the lives of terminally ill people are of less value than are the lives of those who have not been so diagnosed. The Attorney General's interpretation of the CSA alleviates the effects of Oregon's statute and restores to the terminally ill some of the inherent value taken away by the Death with Dignity Act.

B. The Attorney General Has Properly Refused To Apply The "Quality Of Life" Analysis Rejected in *Cruzan v. Director.*

As this Court said in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 280 (1990), "As a general matter, the States – indeed, all civilized nations – demonstrate their commitment to life by treating homicide as a serious crime." "Moreover, the majority of States in this country have laws imposing criminal penalties on one who assists another to commit suicide." *Id.* That commitment to life means that "[a] State may properly decline to make judgments about the 'quality' of life that a particular individual may enjoy, and simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interest of the individual." *Id.* at 282.

Oregon has failed to assert that unqualified right for its citizens, but has instead established a qualified inalienable right to life available only for those who have a quality of life deemed sufficient to warrant protection. Such a conditional right to life is antithetical to this Court's precedents as well as the principles espoused by the Founding Fathers.

The Attorney General, in his role as representative of the United States, must decline to make the "quality of life" judgments inherent in Oregon's Death with Dignity Act. Instead, he must assert the government's unqualified interest in the preservation of life. He has fulfilled this obligation by prohibiting physicians from prescribing controlled substances to assist in suicide and thereby restoring to terminally ill patients full inalienability of their right to life.

C. The Attorney General Has Protected The Most Vulnerable Citizens From Degradation Of Their Right To Life As Provided in *Vacco v. Quill.*

The state's interest in preservation of the right to life is particularly compelling when, as here, it is aimed at protecting the most vulnerable from deprivation of their inalienable right to life. *See Vacco v. Quill,* 521 U.S. 793, 798 (1997). Assisted suicide "is contrary to the prohibition against using the tools of medicine to cause a patient's death." *Id.* at 801. While a physician might use controlled substances in a palliative sense and thereby hasten a terminally ill patient's death, that is a far cry from using controlled substances in a manner intended to cause death. *See id.* at 802. In the former instance, "the physician's purpose and intent is, or may be, only to ease his patient's pain." *Id.* "A doctor who assists a suicide, however, 'must necessarily and indubitably, intend primarily that the patient be made dead'." *Id.* Therefore, while the former can be seen as a legitimate medical purpose – relief from pain – the latter is nothing more than a deliberate attempt to do the ultimate harm – terminate life. *See id.*

Oregon's assisted suicide law ignores this critical distinction and places actions intended to end life on par with actions aimed only at relieving pain. The Attorney General has restored the distinction by ruling that actions aimed at ending life are not legitimate medical purposes under the CSA. In so doing, the Attorney General appropriately followed this Court's precedent in *Vacco* and safeguarded the right to life from the erosive effect of Oregon's law.

The Attorney General has helped reverse Oregon's undermining of this Court's unequivocal protection of the sanctity of human life as enunciated in *Glucksberg, Cruzan*

and *Vacco.* As a result, all citizens of Oregon will continue to enjoy the inalienable right to life regardless of whether they are terminally ill or have some other purported "quality of life" issue.

III. THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA PRESERVES MORE THAN A CENTURY OF STATE PROTECTION OF THE INALIENABLE RIGHT TO LIFE.

For more than 100 years, state courts have protected the right to life as "not only sacred in the estimation of the common law, but ... inalienable." *Martin v. Commonwealth,* 184 Va.1009,1018-1019 (1946).

> The lives of all are equally under the protection of the law, and under that protection to their last moment. The life of those to whom life has become a burden – of those who are hopelessly diseased or fatally wounded – nay, even the lives of criminals condemned to death, are under the protection of the law, equally as the lives of those who are in the full tide of life's enjoyment, and anxious to continue to live.

Blackburn v. State, 23 Ohio St. 146, 163 (1872).

> Purposely and maliciously to kill a human being, by administering to him or her poison, is declared by the law to be murder, irrespective of the wishes or the condition of

the party to whom the poison is administered, or the manner in which, or the means by which, it is administered. The fact that the guilty party intends also to take his own life, and that the administration of the poison is in pursuance of an agreement that both will commit suicide, does not, in a legal sense, vary the case. If the prisoner furnished the poison to the deceased for the purpose and with the intent that she should with it commit suicide, and she accordingly took and used it for that purpose; or, if he did not furnish the poison, but was present at the taking thereof by the deceased, participating, by persuasion, force, threats, or otherwise, in the taking thereof, or the introduction of it into her stomach or body; then, in either of the cases supposed, he administered the poison to her, within the meaning of the statute. Her act of *taking* and *swallowing* it, in his presence and by his direction, was his act of *administering* it.

Id. Similarly, the Michigan Supreme Court found a husband who had mixed poison with water and left it for his wife to drink, at her request, guilty of murder. *People v. Roberts*, 211 Mich. 187, 196 (1920).[5] "He who kills another at his own desire or command is a murderer as much as if he had done it

[5] Overruled in *People v. Kevorkian*, 447 Mich. 436 (1994) as to the proposition that assisted suicide is murder instead of a separate felony. The overruling does not affect the substance of the argument cited above.

of his own hand; and the person killed is not a felo de se." *Id.* In this case, controlled substances are being used instead of poison, and a physician is the third party administering the means of death. However, neither those factors nor the passage of time alter the conclusion inherent in the Attorney General's actions – that legalizing assisted suicide is antithetical to preservation of the inalienable right to life.

California law has prohibited assisted suicide since 1873, and courts have consistently upheld that prohibition based upon preservation of the right to life. *See In re Joseph G.*, 34 Cal.3d 429, 435 (1983). Among the reasons that justify criminalization of assisted suicide is "the belief that the sanctity of life is threatened by one who is willing to participate in taking the life of another, even at the victim's request." *Donaldson v. Lungren*, 2 Cal. App. 4th 1614, 1624 (1992). "No statute or judicial opinion countenances Donaldson's decision to consent to be murdered or to commit suicide with the assistance of others." *Id.* at 1622. The state's interest in punishing assisted suicide is justified not only by the commitment to preserving human life, but also the state's interest in preventing potential abuses. *Id.* at 1624, citing *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261(1990). Such potential abuses are also at the heart of the Attorney General's actions. The aim of the CSA is to regulate the distribution of controlled substances to avoid potential abuses. That includes restricting the prescription of controlled substances by physicians to legitimate medical purposes. The potential abuses inherent in permitting a third party to aid in terminating a person's life means that assisted suicide cannot be regarded as a "legitimate medical purpose," as the Attorney General has rightly determined.

In keeping with the long history of condemnation of assisted suicide, the Alaska Supreme Court rejected

terminally ill patients' requests that their physicians be exempted from Alaska's manslaughter statute criminalizing assisted suicide. *Sampson v. State*, 31 P.3d 88, 89 (Alaska 2001). Citing this Court's rulings in *Glucksberg* and *Cruzan*, the Alaska high court held that "there can be little doubt that substantial state interests underlie the manslaughter statute's general ban of assisted suicide." *Sampson*, 31 P.3d at 96. Chief among these state interests are the interests in preserving life, preventing suicide, protecting vulnerable people, protecting the integrity of the medical profession, and regulating dangerous substances and activities. *Id.* These same state interest underlie the Attorney General's action of banning physicians from participating in assisted suicide through the prescribing of controlled substances.

"In Wisconsin, the interest in preserving life is of paramount significance." *Montalvo v. Borkovec*, 256 Wis. 2d 472, 488 (Wis. App. 2002)(citing *In re L.W.*, 167 Wis. 2d 53, 90 (1992)). The interest in preserving life encompasses "both the interest in preserving the patient's life and the interest in preserving the sanctity of all life." *In re L.W.*, 167 Wis.2d at 90. Here the Attorney General has acted to preserve the lives of terminally ill patients. In so doing, the Attorney General has help halt a gradual erosion of the right to life that, if left unchecked could threaten the sanctity of all life.

The Nevada Supreme Court agrees that "[t]he State's interest in preserving life is both fundamental and compelling. Indeed, it constitutes a basic purpose for which governments are formed." *McKay v. Bergstedt*, 106 Nev. 808, 816 (1990). The State's interest in preserving all human life is neither abstract nor indirect and "should not be suspended or minimized under any conditions." *Id.* Oregon's Death with Dignity Act represents just such a minimization, as the right to life becomes dependent upon whether the life is of

sufficient "quality" or expected duration to warrant being protected. Banning the prescription of controlled substances to prevent such a minimization restores the fundamental and inalienable nature of the right to life.

Affirming that every person has a right to life which cannot be denied absent clear and convincing evidence of the express will of the affected person, New York's highest court rejected the "quality of life" analysis inherent in Oregon's assisted suicide law. *See Matter of O'Connor*, 72 N.Y.2d 517, 530 (1988). In *O'Connor*, the court re-affirmed its "fundamental commitment to the notion that no person or court should substitute its judgment as to what would be an acceptable quality of life for another" when it granted the hospital's request to insert a nasogastric feeding tube into a incompetent patient. *Id.* Questions regarding which rights should prevail must be resolved in favor of life. *Id.* The Attorney General's interpretation of the CSA is just such a resolution, as controlled substances are used only to preserve life, not promote death.

New Hampshire's Supreme Court affirmed that the State has compelling interests in preserving life and preventing suicide which can overcome individuals' rights to privacy and self-determination. *In re Caulk*, 125 N.H. 226, 232 (1984). People should not be placed in the precarious position of choosing between their statutory and constitutional obligations to preserve life and contravening legal duties. *Id.* at 231. This is the precise dilemma that would be faced by physicians under Oregon's assisted suicide law. They would be placed in the precarious position of having to choose between their obligation to preserve life and their legal duty to assist patients under Oregon law. Recognizing, as did the New Hampshire Supreme Court, that no one should be placed in such a situation, the Attorney General appropriately

dissolved the dilemma by prohibiting physicians from using controlled substances to assist a patient in committing suicide.

The Attorney General's interpretation of the CSA to prohibit prescriptions of controlled substances for assisted suicide helps preserve the tradition of state protection of the sanctity of human life from the threatened erosion present in Oregon's Death with Dignity Act.

IV. THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA PROPERLY PROTECTS THE INTEGRITY OF THE MEDICAL PROFESSION AND ITS COMMITMENT TO HEALING AND THE PRESERVATION OF LIFE

The Attorney General's interpretation of the CSA also comports with his duty to protect the integrity of the medical profession and its commitment to the sanctity of human life.

The American Medical Association has maintained a persistent stance against assisted suicide as the antithesis of the physician's calling. "The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides physicians." AMA letter in support of H.R. 1003, 143 CONG REC. S3249-01 (April 15, 1997). "The AMA continues to stand by its ethical principle that physician-assisted suicide is fundamentally incompatible with the physician's role as healer...." *Id.* Indeed, the AMA has consistently re-affirmed its ethical prohibition against physician-assisted suicide. *See* AMA Code of Medical Ethics §2.211 (1994). Physician-assisted suicide has long been viewed as outside the realm of legitimate health care. Brief for the American Medical Association at 4, *Washington v. Glucksberg*, 521 U.S. 702 (1997). Therefore, as the Attorney

General determined, the prescription of controlled substances for assisted suicide is not a legitimate medical practice under the CSA, and physicians cannot use their federally issued controlled substances licenses for such purposes.

As this Court said in *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997), "The State also has an interest in protecting the integrity and ethics of the medical profession." Citing the AMA's Code of Medical Ethics §2.211, this Court found that Washington was justified in banning assisted suicide since physician-assisted suicide could undermine the trust that is essential to the doctor-patient relationship by blurring the line between healing and harming.

Similarly, the Attorney General is justified in prohibiting physicians from participating in assisted suicides and thereby undermining the inherent trust in the doctor-patient relationship.

The Nevada Supreme Court agreed that, "The State has an unquestioned duty to see that the integrity of the medical profession is preserved and that it is never allowed to become an instrument for the selective destruction of lives deemed to have little utility." *McKay v. Bergstedt* 106 Nev. 808, 824 (1990). The Attorney General has done just that by prohibiting physicians from participating in Oregon's qualified right to life through the prescribing of controlled substances for assisted suicide.

CONCLUSION

Oregon's Death with Dignity Act's attempted validation of physician-assisted suicide is antithetical to preservation of the inalienable right to life guaranteed by the Declaration of Independence and U.S. Constitution. The Attorney General has appropriately responded to that potential

degradation of the right to life by prohibiting physicians from prescribing controlled substances for assisted suicides. Far from being a usurpation of the Attorney General's powers, the prohibition against assisted suicide is a recognition of the continuing importance of the inalienable right to life granted to all men by their Creator.

For these reasons, the lower court ruling must be reversed.

Respectfully Submitted,

Mathew D. Staver
(Counsel of Record)
Erik W. Stanley
Anita L. Staver
Rena M. Lindevaldsen
Mary E. McAlister
LIBERTY COUNSEL
210 East Palmetto Avenue
Longwood, FL 32750
Attorneys for Amicus Curiae

(16)

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IN THE SUPREME COURT OF THE UNITED STATES

ALBERTO GONZALES, ATTORNEY GENERAL, *et al.*,
Petitioners,

v.

STATE OF OREGON, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF *AMICI CURIAE* OF THE UNITED STATES CONFERENCE OF CATHOLIC BISHOPS, CALIFORNIA CATHOLIC CONFERENCE, OREGON CATHOLIC CONFERENCE, WASHINGTON STATE CATHOLIC CONFERENCE; CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES, AND LUTHERAN CHURCH-MISSOURI SYNOD IN SUPPORT OF PETITIONERS

Mark E. Chopko*
General Counsel
Michael F. Moses
Associate General Counsel
United States Conference
of Catholic Bishops
3211 Fourth St., N.E.
Washington, DC 20017
(202) 541-3300
*Counsel of Record

May 9, 2005

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF *AMICI*.	1
SUMMARY OF ARGUMENT.	3
ARGUMENT.	5
I. Assisting Suicide and Treating Pain Are Fundamentally Different	5
II. Enforcing the Difference Between Relieving Pain and Assisting Suicide Has Led to Improvements in Patient Care; Blurring the Distinction Threatens Patients and Patient Care	12
CONCLUSION.	24

TABLE OF AUTHORITIES

PAGE

CASES

Harris v. McRae, 448 U.S. 297 (1980). 10

Oregon v. Ashcroft, 192 F.Supp.2d 1077 (D. Or. 2002) 4

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004). 4

Vacco v. Quill, 521 U.S. 793 (1997). 5

Washington v. Glucksberg, 521 U.S. 702 (1997). 6, 15

STATUTES

21 U.S.C. § 823. 10

42 U.S.C. § 14402 11

Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, 111 Stat. 23 (April 30, 1997) 11, 12

Ariz. Rev. Stat. § 13-1103 22

Ga. Code Ann. § 16-5-5 22

Ill. Comp. Stat. ch. 720, § 5/12-31. 22

Iowa Code §§ 707A.1 to 707A.3 18

Kan. Stat. Ann. § 21-3406. 18

Kan. Stat. Ann. § 60-4403. 18

Ky. Rev. Stat. Ann. §§ 216.302 to 216.308. 18

La. Rev. Stat. Ann. § 14:32.12 18

Md. Ann. Code art. 27, § 416 18

Md. Crim. Code §§ 3-101 to 3-104. 18

Mich. Comp. Laws § 750.329a 22

Ohio Rev. Code §§ 3795.01 to 3795.03. 18

Okla. Stat. tit. 63, §§ 3141.1 to 3141.8. 18

R.I. Gen. Laws §§ 11-60-1 to 11-60-5 18

S.C. Code Ann. § 16-3-1090 18

S.D. Codified Laws §§ 22-16-37.1 to 22-16-37.7 18

Tenn. Code Ann. § 39-13-216 18

Va. Code Ann. § 8.01-622.1. 18

2005 S.D. Laws, ch. 120 (SB 43) 18

LEGISLATIVE HISTORY

143 Cong. Rec. S3258-60 (April 16, 1997). 11, 12

Assisted Suicide in the United States, Hearing before the Subcommittee on the Constitution of the House Committee on the Judiciary, 104th Cong., 2d Sess. (1996). 5

FEDERAL REGISTER

55 Fed. Reg. 37579 (Sept. 12, 1990). 11

59 Fed. Reg. 46063 (Sept. 6, 1994). 11

60 Fed. Reg. 56354 (Nov. 8, 1995). 10

66 Fed. Reg. 56607 (Nov. 9, 2001). 3, 4

OTHER AUTHORITIES

American Pain Society, PRINCIPLES OF ANALGESIC USE IN THE TREATMENT OF ACUTE PAIN AND CANCER PAIN (3d ed. 1992) 7

Marcia Angell, M.D., *The Quality of Mercy*, 306 New Eng. J. Med. 98 (Jan. 14, 1982). 7

John Arras, *Physician-Assisted Suicide: A Tragic View*, 13 J. of Contemp. Health L. & Pol'y 361 (Spring 1997) 13

Brief of the American Medical Association, the American Nurses Association, and the American Psychiatric Association, *et al.*, as *Amici Curiae* in Support of Petitioners, *Vacco v. Quill*, 521 U.S. 793 (1997) (No. 95-1858) 9

Brief of the United States as *Amicus Curiae* Supporting Petitioners, *Vacco v. Quill*, 521 U.S. 793 (1997) (No. 95-1858) 12

Howard Brody, M.D., *Physician-Assisted Suicide in the Courts: Moral Equivalence, Double Effect, and Clinical Practice*, 82 Minn. L. Rev. 939 (April 1998) 6, 14

Elizabeth Cassidy, *et al.*, "As Life Ends: Professional Care Givers on Terminal Care and Euthanasia," in EUTHANASIA AND ASSISTED SUICIDE: THE CURRENT DEBATE 52 (Ian Gentles, ed., 1995) 8

Felicia Cohn, Ph.D., and Joanne Lynn, M.D., "Vulnerable People: Practical Rejoinders to Claims in Favor of Assisted Suicide," in THE CASE AGAINST ASSISTED SUICIDE: FOR THE RIGHT TO END-OF-LIFE CARE 238 (Kathleen Foley, M.D., and Herbert Hendin, M.D., eds., 2002). 7, 8, 14

Donna L. Dickenson, *Are Medical Ethicists Out of Touch: Practitioner Attitudes in the US and UK Towards Decisions at the End of Life*, 26 J. Med. Ethics 254 (2000) 10

Drug Enforcement Administration, U.S. Department of Justice, Statistics on Individual State Consumption of Morphine. 18

Ezekiel J. Emanuel, M.D., *et al.*, *Attitudes and Practices of U.S. Oncologists Regarding Euthanasia and Physician-Assisted Suicide*, 133 Annals of Internal Medicine 527 (October 2000). 13

Susan Anderson Fohr, *The Double Effect of Pain Medication: Separating Myth from Reality*, 1 J. of Palliative Med. 315 (1998). 6

Kathleen Foley, M.D., and Herbert Hendin, M.D., "The Oregon Experiment," in THE CASE AGAINST ASSISTED SUICIDE: FOR THE RIGHT TO END-OF-LIFE CARE 144 (Kathleen Foley, M.D., and Herbert Hendin, M.D., eds., 2002) 16

Erik K. Fromme, M.D., *et al.*, *Increased Family Reports of Pain or Distress in Dying Oregonians: 1996 to 2002*, 7 J. of Palliative Med. 431 (2004). . . 16, 17

HANDBOOK OF PAIN RELIEF IN OLDER ADULTS: AN EVIDENCE-BASED APPROACH (F. Michael Gloth, M.D., ed., 2004). 18

House of Lords, Select Committee on the Assisted Dying for the Terminally Ill Bill, Volumes I and II: Report and Evidence (April 4, 2005) 15, 16

2 House of Lords, Session 1993-1994 Report of Select Committee on Medical Ethics (1994) . . . 15

Michael H. Levy, M.D., *Pharmacologic Treatment of Cancer Pain*, 335 New Eng. J. Med. 1124 (Oct. 10, 1996) 8

The New York State Task Force on Life and the Law, WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT (April 1997 Supplement). . . . . *passim*

Oregon Department of Human Services, Fourth Annual Report on Oregon's Death with Dignity Act (Feb. 6, 2002). 17

Oregon Department of Human Services, Sixth Annual Report on Oregon's Death with Dignity Act (March 10, 2004). 17

Oregon Department of Human Services, Seventh Annual Report on Oregon's Death with Dignity Act (March 10, 2005). 17

Edmund Pellegrino, M.D., and Daniel Sulmasy, M.D., *The Rule of Double Effect: Clearing Up the Double Talk*, 159 Arch. Intern. Med. 545 (1999) . . 9, 10, 14

Susan W. Tolle, M.D., *et al.*, *Trends in Opioid Use Over Time: 1997 to 1999*, 7 J. of Palliative Med. 39 (2004). 17

Vacco v. Quill, No. 95-1858 (U.S.), Transcript of Oral Argument, *reprinted in* 12 Issues in Law and Med. 417 (Spring 1997). 15

Webster's New World Dictionary (3d College ed. 1988). 3

Zbigniew Zylicz, M.D., "Palliative Care and Euthanasia in the Netherlands: Observations of a Dutch Physician," in THE CASE AGAINST ASSISTED SUICIDE: FOR THE RIGHT TO END-OF-LIFE CARE 122 (Kathleen Foley, M.D., and Herbert Hendin, M.D., eds., 2002) 15

INTEREST OF *AMICI* [1]

The United States Conference of Catholic Bishops, California Catholic Conference, Oregon Catholic Conference, Washington State Catholic Conference, Catholic Health Association of the United States, and Lutheran Church-Missouri Synod join here as *amici curiae* in support of Petitioners, the Attorney General of the United States, *et al.* The Attorney General's conclusion that there is a difference between assisting suicide and managing pain, and that the former is not a legitimate medical purpose within the meaning of the Controlled Substances Act and regulations while the latter is, is not only eminently reasonable but also supported by longstanding medical practice and past interpretation of the Act. Enforcing the distinction leads to improvements in patient care. Blurring the distinction has been harmful to patients and jeopardized their care. Government does not serve the public interest or the common good by facilitating the killing of innocent people, regardless of their medical condition. The Attorney General's construction of federal law is reasonable and entitled to deference.

Individual statements of interest follow.

The United States Conference of Catholic Bishops is a nonprofit corporation organized under the laws of the District of Columbia. Its members are the active Catholic Bishops in the United States. The Bishops of California, Oregon, and Washington State are also members of the California, Oregon,

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[1] Pursuant to this Court's Rule 37.6, counsel for a party did not author this Brief in whole or in part. No person or entity, other than the United States Conference of Catholic Bishops, made a monetary contribution to the preparation or submission of this Brief. The parties have consented to the filing of this Brief. Letters of consent are filed herewith.

and Washington State Catholic Conferences, respectively. Through the Conferences, the Bishops speak collegially on matters affecting the Catholic Church, its people, and society as a whole. The Conferences advocate and promote the pastoral teaching of the Church on many diverse issues, including the sanctity and dignity of human life. The ethical distinction made in law and medicine between legitimate treatment of pain and assisting suicide, a distinction that underlies the Attorney General's action in this case, has been influenced by concepts of intentionality and moral responsibility that have their foundation in the Church's centuries-old teaching. The Conferences are therefore especially well-suited to address this distinction and its importance to the integrity of the medical profession and to important societal interests in promoting health and relieving pain and suffering.

The Catholic Health Association of the United States ("CHA") is the national leadership organization of the Catholic health ministry, engaged in the strategic directions of mission, ethics and advocacy. This ministry, comprised of more than 2,000 nonprofit Catholic health care systems, sponsors, facilities, health plans, and related organizations, is rooted in and informed by a deeply held commitment to promote and defend human life and human dignity. CHA's interest in this case stems from its concern for the need to protect vulnerable persons; to ensure appropriate care for dying persons; to preserve the integrity of the health care professions; to strengthen the bonds of community; and to preserve the integrity of the Catholic health ministry.

The Lutheran Church-Missouri Synod (the "Synod") is the second largest Lutheran denomination in the United States. It has about 6,100 member congregations, with about 2.5 million baptized members. In 1995 the congregations of the Synod

passed a resolution expressing the Synod's objection "to medical personnel having any part in actively inducing death, even at the patient's request," and resolved "to speak against any attempt to legalize physician-assisted suicide." The Synod fully agrees with the Attorney General's conclusion that assisted suicide is not a legitimate medical purpose, but that pain management is. In a report published by the Synod's Commission on Theology and Church Relations, the Commission distinguished between assisted suicide ("euthanasia") and pain management: "Euthanasia, in its proper sense, is a synonym for mercy killing, which involves suicide and/or murder. It is, therefore, contrary to God's Law.... Administering pain-killing medications, even at the risk of shortening life, is permissible, since this does not entail the choice of death as either a means or an end."

SUMMARY OF ARGUMENT

"[A]ssisting suicide is not a 'legitimate medical purpose.'" 66 Fed. Reg. 56607, 56608 (Nov. 9, 2001). That simple declaration is at the root of this litigation. Indeed, it would appear to be a self-evident declaration. Medicine by its very definition aims to prevent illness, to heal, and to alleviate pain.[2] Taking a human life accomplishes none of these objectives. To say that it does creates an inherent contradiction, like saying that the legitimate practice of law includes helping clients break the law. The analogy is apt because helping to kill is precisely the opposite of what medicine is and does. Cooperating with killing positively impedes the overarching goods to which medicine is devoted. This is as true on a practical level as it is in principle, for recourse to legitimate care of the dying, including palliative care, is advanced when ethics and law forbid doctors to help

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[2] *See* Webster's New World Dictionary (3d College ed. 1988) (defining medicine as "the science and art of diagnosing, treating, curing, and preventing disease, relieving pain, and improving and preserving health").

patients take their own lives. Allowing intentional lethal acts will not make it easier for patients to obtain the medical care they need, but will only impede their ability to obtain such care. What virtually every state regards as a crime, indeed as a form of homicide, does not become "medicine" simply because the perpetrator is a doctor, the patient is terminally ill, or one state has decided to rescind its own criminal penalties for the act.

The Attorney General correctly concluded that assisting suicide is not a legitimate medical purpose, but that pain management is. 66 Fed Reg. 56607, 56608 (Nov. 9, 2001). It is apparent that the distinction between assisting suicide and managing pain was not always understood and appreciated by the lower courts hearing this case. *Oregon v. Ashcroft*, 192 F.Supp.2d 1077, 1079 (D. Or. 2002) (suggesting that assisted suicide serves the interest in "end[ing] … suffering"); *Oregon v. Ashcroft*, 368 F.3d 1118, 1123 n.5 (9th Cir. 2004) ("it is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives").

We file this brief to explain the ethical and legal basis for the Attorney General's twofold conclusion that assisted suicide is not a legitimate medical purpose for use of controlled substances while pain management is. In Part I, we explain the fundamental difference between treating pain and assisting suicide, addressing the misconception that assisting suicide is simply a means of treating pain. We also explain how this distinction, and the understanding of assisted suicide as being outside the scope of legitimate medical practice, is consistent with longstanding tenets of the medical profession and past interpretation and enforcement of the Controlled Substances Act, a fact overlooked by the lower courts. In Part II, we explain how recognizing the distinction between treating pain and assisting suicide, and prohibiting the latter, has led to significant improvements in

palliative care and in the ability of physicians to care for dying patients, while obliterating the distinction, as the opinion below would do, could have a deleterious impact on pain management and palliative care.

ARGUMENT

1. Assisting Suicide and Treating Pain Are Fundamentally Different.

Pain control and assisted suicide fundamentally differ in both intent and effect. A physician's intent in administering pain-killing drugs is simply "to ease his patient's pain," not to cause death. *Vacco v. Quill*, 521 U.S. 793, 802 (1997). A doctor who assists a suicide, however, "must, necessarily and indubitably, intend primarily that the patient be made dead." *Id.* at 802, quoting Assisted Suicide in the United States, Hearing before the Subcommittee on the Constitution of the House Committee on the Judiciary, 104th Cong., 2d Sess., 367 (1996). This distinction has long been recognized in criminal law. If a patient dies after receiving palliative care, an attending physician is not liable for murder for he or she did not intend death. When a doctor accedes to a patient's request to provide the means of committing suicide, however, death is always the intention.

Assisted suicide and palliative care also have radically different consequences. Assisted suicide by definition is always deadly when it succeeds. Palliative care, however, does not kill people.

Indeed, at one time, concerns were voiced that pain medication might cause respiratory depression leading to a patient's death. "More recent experience … has shown that respiratory depression, although theoretically possible and

occasionally encountered, very seldom is of practical concern when physicians exercise care in adjusting dosages and observing patients for responses to medication." Howard Brody, M.D., *Physician-Assisted Suicide in the Courts: Moral Equivalence, Double Effect, and Clinical Practice*, 82 Minn. L. Rev. 939, 947 (April 1998). Today the risk of respiratory depression resulting from pain management is "more myth than fact," for there is "little evidence that the use of medication to control pain hastens death." Susan Anderson Fohr, *The Double Effect of Pain Medication: Separating Myth from Reality*, 1 J. of Palliative Med. 315 (1998) (quoting the abstract).

In the April 1997 Supplement to its widely cited 1994 report on assisted suicide and euthanasia,[3] the New York State Task Force on Life and the Law likewise rejected the claim that aggressive pain management results in death from depression of respiration or other side effects:

> While high doses of morphine can depress respiration when administered to patients who have not developed tolerance to the drug, physicians who treat patients with morphine for the relief of pain increase the doses gradually, so that tolerance can develop.... [T]here appears to be no limit to tolerance when the drug is administered properly. The claim that the use of morphine at properly titrated levels "hastens" patients' deaths, based on the effects of high doses of morphine on patients who have *not* developed tolerance, is entirely unfounded.

[3] *E.g., Washington v. Glucksberg*, 521 U.S. 702, 719 (1997) (relying on the 1994 report).

IN THE MEDICAL CONTEXT 17 (April 1997 Supplement) (original emphasis) (internal quotation marks and citations omitted). Other authorities similarly note that when dosages are properly calibrated to relieve pain, death as a side-effect is extremely rare, if it occurs at all:

> As commonly used, pain medications rarely accelerate the patient's death. Patients using opioids chronically do not experience respiratory depressant side effects at doses that are effective in suppressing pain. Once the patient is habitually taking opioids, only a quite extraordinary dose would be lethal. Only for patients who have received no opioids is the respiratory depressant effect present at analgesic doses, and few dying patients are in this situation.

Felicia Cohn, Ph.D., and Joanne Lynn, M.D., "Vulnerable People: Practical Rejoinders to Claims in Favor of Assisted Suicide," in THE CASE AGAINST ASSISTED SUICIDE: FOR THE RIGHT TO END-OF-LIFE CARE 238, 249 (Kathleen Foley, M.D., and Herbert Hendin, M.D., eds., 2002); *see also* Marcia Angell, M.D., *The Quality of Mercy*, 306 New Eng. J. Med. 98, 99 (Jan. 14, 1982) ("Addiction among patients who receive narcotics for pain is exceedingly unlikely; the incidence is probably no more than 0.1 per cent.... The incidence of serious respiratory depression in patients who receive narcotics for pain is similarly low. As tolerance develops to the analgesic effects of narcotics, so it does to the respiratory effects. No more than 1 percent of patients who receive narcotics for pain develop serious respiratory depression."); American Pain Society, PRINCIPLES OF ANALGESIC USE IN THE TREATMENT OF ACUTE PAIN AND CANCER PAIN 23 (3d ed. 1992) ("[R]espiratory depression is rare in patients who have been receiving chronic opioid treatment");

Michael H. Levy, M.D., *Pharmacologic Treatment of Cancer Pain*, 335 New Eng. J. Med. 1124, 1129 (Oct. 10, 1996) ("Appropriate titration of the opioid dose rarely results in respiratory depression or cardiovascular collapse"); Elizabeth Cassidy, *et al.*, "As Life Ends: Professional Care Givers on Terminal Care and Euthanasia," in EUTHANASIA AND ASSISTED SUICIDE: THE CURRENT DEBATE 52 (Ian Gentles, ed., 1995) ("[I]t is well known by practitioners in the field of terminal care that deaths from narcotics are extremely rare in terminal patients").

If death results, it is unintended. When, for example, a person undergoes surgery for a serious or life-threatening illness, the fact that she may die on the operating table obviously does not mean that her death was intended or that the surgeon should be charged with murder. The New York State Task Force made the same point:

> [T]he fact that morphine drips may accelerate patients' deaths in some cases does not make their use equivalent to assisted suicide or euthanasia. Just as a surgeon might undertake risky heart surgery knowing that the patient may die on the table, so the conscientious physician can risk suppressing the patient's respiratory drive and thus hastening death so long as she is pursuing a valid medical objective and there are no better (less risky) options at hand.

WHEN DEATH IS SOUGHT, at 17 (April 1997 Supplement) (internal quotation marks and citations omitted); *see also* Cohn & Lynn, *supra* at 249 ("Even if a physician's act may hasten death, the physician is not acting to ensure an earlier death").[4]

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[4]Similar differences in intent and causation undergird the difference between assisted suicide and withdrawal of life-sustaining treatment. The

Intentionality is important both to medicine and to law, and undergirds the ethical and practical distinctions at issue here.[5]

American Medical Association recognizes:

> In respecting a patient's decision to have treatment withheld or withdrawn, the physician is acting squarely within the historic parameters of the profession. The physician is fulfilling his or her role as someone who responds to the patient's needs by providing medical treatment.... Although the act of withholding or withdrawing medical treatment may lead to death, the intent of the physician in so acting is not to cause death, but to respect the patient's essential right to decide if and when to let the disease process take its course.
>
> Conversely, when the physician responds affirmatively to a request for help in committing suicide, the physician's intent is only to help the patient in taking his or her life. The physician thus acts with intent to kill.

Brief of the American Medical Association, the American Nurses Association, and the American Psychiatric Association, *et al.*, as *Amici Curiae* in Support of Petitioners, at 20, *Vacco v. Quill*, 521 U.S. 793 (1997) (No. 95-1858).

[5]Medical ethics sometimes discusses the difference between the intended and unintended effects of a procedure in terms of the "principle of double effect." An action that unavoidably may have both a good effect and a bad effect is justifiable if the action: (1) is not itself immoral; (2) is intended only to cause the good effect, though the bad effect may be foreseen; (3) does not bring about the good effect only by means of the possible bad effect (*e.g.*, deliberately causing death to end pain, with the argument that dead patients cannot feel pain); and (4) is undertaken for a proportionately serious reason. Providing pain medication in dosages necessary to relieve intractable pain fulfills these criteria; euthanasia and physician-assisted suicide do not. Edmund Pellegrino, M.D., and Daniel Sulmasy, M.D., *The Rule of Double Effect: Clearing Up the Double Talk*, 159 Arch. Intern. Med. 545-50 (1999).

The principle of double effect has been accepted and used in medical practice for many years. One recent survey finds the principle so widely

The distinction between relieving pain and assisting suicide is also consistent with past interpretation and enforcement of the Controlled Substances Act. Well before the Attorney General issued his directive on assisted suicide in November 2001, the Drug Enforcement Administration ("DEA") had considered facilitating suicide to be inconsistent with "public health and safety" under the Controlled Substances Act. 21 U.S.C. § 823. In 1995, for example, the DEA denied an application for a Certificate of Registration in a case in which the registrant had prescribed 100 tablets of Darvocet to a patient who, a few days earlier, had made a serious suicide attempt. 60 Fed. Reg. 56354 (Nov. 8, 1995). The physician's conduct, which one expert likened to "handing [the patient] a loaded gun," facilitated the patient's suicide by overdose. *Id.* at 56355. Applying the Act's clear federal standard for denying such applications,[6] a standard that is not dependent on state law, the DEA concluded that "[t]he threat to the public health and safety" of the registrant's

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accepted among practicing British and American health professionals, particularly in the context of controlling pain and withdrawing life-sustaining treatment, that the authors conclude that those who criticize the principle may be "out of touch" with modern medicine. Donna L. Dickenson, *Are Medical Ethicists Out of Touch: Practitioner Attitudes in the US and UK Towards Decisions at the End of Life*, 26 J. Med. Ethics 254-60 (2000). Of course, "[t]he argument that [the principle of double effect] should be rejected out of hand simply because it originated with a particular religious tradition is completely unwarranted." Pellegrino & Sulmasy, *supra* at 549. It would be comparable to rejecting homicide laws because they happen to coincide with the Fifth Commandment. *Cf. Harris v. McRae*, 448 U.S. 297, 319 (1980) ("That the Judaeo-Christian religions oppose stealing does not mean that a State or the Federal Government may not, consistent with the Establishment Clause, enact laws prohibiting larceny.").

[6] 21 U.S.C. 823(f)(5) (requiring consideration of whether a practitioner has engaged in "conduct which may threaten the public health and safety" in deciding whether registration would be "inconsistent with the public interest").

prescribing practices "directly impacts upon the public interest." *Id.* at 56356. *See also* 55 Fed. Reg. 37579, 37580 (Sept. 12, 1990) (denying DEA registration of registrant whose prescriptions facilitated drug addiction ultimately leading to an attempted suicide); 59 Fed. Reg. 46063, 46065 (Sept. 6, 1994) (denying DEA registration where registrant's conduct included providing anabolic steroids to a patient who ten months earlier had attempted suicide).

The fundamental distinction between assisting suicide and relieving pain is also recognized elsewhere in federal law. Under the Assisted Suicide Funding Restriction Act of 1997 ("ASFRA"), Pub. L. No. 105-12, 111 Stat. 23 (April 30, 1997), federal funds may not be used to pay for items and services the purpose of which is to cause or assist in causing the suicide of any individual. By its express terms, nothing in ASFRA applies to, or imposes any limitation on, "the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason." 42 U.S.C. § 14402. In the words of a sponsor, ASFRA was designed to recognize "the critical difference between the administration of pain medication and physician-assisted suicide," even in the rare case where administering the level of medication necessary to relieve pain may have a "secondary effect" of hastening death. 143 Cong. Rec. S3260 (daily ed. April 16, 1997) (statement of Sen. McConnell).

In declaring its support for ASFRA, the American Medical Association emphasized the difference between taking life and relieving pain:

> The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides physicians. The AMA continues to stand by its ethical principle that physician-assisted suicide is fundamentally incompatible with the physician's role as healer and that physicians must instead aggressively respond to the needs of patients at the end of life.

143 Cong. Rec. S3258 (daily ed. April 16, 1997). Thus, since 1997, with the support of organizations representing the medical profession, all federal health programs have included pain management in the scope of legitimate medical procedures while explicitly excluding assisted suicide from that scope.[7]

In light of the widely- and long-recognized distinction between relieving pain and assisting suicide, the Attorney General properly concluded that pain management is a legitimate medical purpose for use of federally controlled drugs and that assisting suicide is not.

2. Enforcing the Difference Between Relieving Pain and Assisting Suicide Has Led to Improvements in Patient Care; Blurring the Distinction Threatens Patients and Patient Care.

There is evidence that when ethics and law maintain the distinction between palliative care and assisted suicide, and the latter is prohibited, patient care improves. Conversely, there is

[7]ASFRA confirmed the federal government's existing practice for, even prior to ASFRA's enactment, federal programs did not permit physicians to administer or prescribe medication for the purpose of ending a patient's life. *See* Brief of the United States as *Amicus Curiae* Supporting Petitioners at 2-3, *Vacco v. Quill*, 521 U.S. 793 (1997) (No. 95-1858).

evidence that when the distinction is blurred, as in the Netherlands and Oregon, patients and patient care suffer.

Failure to draw the distinction has a chilling effect on pain management and palliative care. The New York State Task Force writes:

> Just as conflating the refusal of treatment with assisted suicide is likely to undermine patients' ability to control their medical treatment, telling physicians that an unintended death resulting from the provision of necessary palliative treatment is a form of covert euthanasia is likely to result in many more patients experiencing unrelieved pain. As John Arras has pointed out, "many physicians would sooner give up their allegiance to adequate pain control than their opposition to assisted suicide and euthanasia." Characterizing the provision of pain relief as a form of euthanasia may well lead to an increase in needless suffering at the end of life.

WHEN DEATH IS SOUGHT 18 (April 1997 Supplement), quoting John Arras, *Physician-Assisted Suicide: A Tragic View*, 13 J. of Contemp. Health L. & Pol'y 361, 379 n.69 (Spring 1997). The same view is expressed by the authors of a study of attitudes about assisted suicide among oncologists. A reluctance to practice effective pain relief, the authors commented, "may be encouraged by proponents of euthanasia who have argued that there is no difference between increasing morphine for pain relief and euthanasia." Ezekiel J. Emanuel, M.D., *et al.*, *Attitudes and Practices of U.S. Oncologists Regarding Euthanasia and Physician-Assisted Suicide*, 133 Annals of Internal Medicine 527, 530 (October 2000). Dr. Howard Brody

has suggested that pain management is best served by clearly distinguishing it from assisted suicide. He writes:

> Clinicians must believe, to some degree, in a form of the principle of double effect in order to provide optimal symptom relief at the end of life.... A serious assault on the logic of the principle of double effect could do major violence to the (already reluctant and ill-informed) commitment of most physicians to the goals of palliative care and hospice.

Brody, *supra* at 959. *See also* Pellegrino & Sulmasy, *supra* at 545 (the "rule of double effect ... encourages optimal care of the dying," while "[u]ndermining the rule ... has the potential to affect the care of the dying adversely").

The patients most likely to suffer from any confusion between controlling pain and assisting suicide are, of course, those who are already marginalized in the delivery and receipt of health care services. The New York State Task Force notes that any policy allowing assisted suicide

> will be implemented through the prism of social inequality and bias that characterizes the delivery of services in all segments of our society, including health care. The practices will pose the greatest risks to those who are poor, elderly, isolated, members of a minority group, or who lack access to good medical care.

WHEN DEATH IS SOUGHT 4-5 (April 1997 Supplement); *see also* Cohn & Lynn, *supra* at 260 ("abuse [from legalization of assisted suicide] is a real risk, especially among those who are

elderly, frail, disabled, and economically disadvantaged").

Conversely, patient care improves in jurisdictions where the distinction between pain management and assisted suicide is recognized and the latter is prohibited. In his concurring opinion in *Glucksberg*, Justice Breyer cited a report of the House of Lords indicating that "the number of palliative care centers in the United Kingdom, where physician assisted suicide is illegal, significantly exceeds that in the Netherlands, where such practices are legal." 521 U.S., at 792, citing 2 House of Lords, Session 1993-1994 Report of Select Committee on Medical Ethics 113 (1994).[8] A Dutch hospice expert observes that while palliative care has developed rapidly in English-speaking countries, the acceptance and legalization of assisted suicide and euthanasia in the Netherlands have marginalized hospice and stifled the development of palliative care practices in that country. Zbigniew Zylicz, M.D., "Palliative Care and Euthanasia in the Netherlands: Observations of a Dutch Physician," in THE CASE AGAINST ASSISTED SUICIDE, *supra* at 122, 124, 141-143.[9]

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[8]Justice Breyer observed in oral argument in *Quill* that England, which forbids assisted suicide, has 185 palliative care centers, as compared with three such centers in Holland, which permits assisted suicide. *Vacco v. Quill*, No. 95-1858 (U.S.), Transcript of Oral Argument, *reprinted in* 12 Issues in Law and Med. 417, 437 (Spring 1997).

[9]A more recent report of a House of Lords committee taking up the question of end-of-life care does not dispel this negative judgment about the quality of palliative care in the Netherlands. Palliative care, the committee found, "is not recognized in [t]he Netherlands as a clinical speciality," and despite some increase in the number of palliative care units there, medical personnel "are mostly just continuing what they were doing – in the sense that there is no real specialist understanding, knowledge and practice of palliative care." House of Lords Select Committee on the Assisted Dying for the Terminally Ill Bill, Volume 1: Report, 66 ¶¶ 183, 185 (April 4, 2005). There is also anecdotal evidence that the practice of

The picture in Oregon is similar. A 1999 survey of Oregon physicians who received requests for assisted suicide "gives us some picture of the inadequacy of palliative care consultation" there. Kathleen Foley, M.D., and Herbert Hendin, M.D., "The Oregon Experiment," in THE CASE AGAINST ASSISTED SUICIDE, *supra* at 144, 153-54. "In more than half of the 142 cases for which physicians supplied information, including eighteen of the twenty-nine patients who by that time had been given prescriptions for lethal medications and nine of the seventeen who had died from taking the prescribed medication, there was no palliative care intervention of any kind." *Id.* at 154. Significantly, physicians who assist suicide in Oregon "are not required … to be knowledgeable about how to relieve either physical or emotional suffering in terminally ill patients," nor does Oregon require "courses in pain management, palliative care, or the evaluation of a suicidal patient…." *Id.* at 145.

More recent studies show a significant statewide increase in reports of moderate to severe pain among patients in the last week of life after Oregon's law permitting physician-assisted suicide went into effect in October 1997. In Oregon hospitals, the prevalence of family-reported moderate to severe pain or distress in the last week of life rose from 33% in 1996-97 to 54% in 1998. Erik K. Fromme, M.D., *et al.*, *Increased Family Reports of Pain or Distress in Dying Oregonians: 1996 to 2002*, 7 J. of Palliative Med. 431, 432 (2004). In non-hospital settings (private homes, nursing homes, foster care facilities, assisted

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euthanasia and assisted suicide in the Netherlands has inhibited the development of medical and palliative care skills in that country. In one reported case, a general practitioner did not know how to treat a patient with a gastrointestinal obstruction who was refusing euthanasia because in all previous cases the physician had "treated" patients with this condition by killing the patient. House of Lords, Select Committee on the Assisted Dying for the Terminally Ill Bill, Volume II: Evidence, 449 (April 4, 2005).

living, and inpatient hospices), the prevalence of moderate to severe pain or distress for Oregon patients in the last week of life rose from 30.8% in the period November 1996-December 1997 to 48% in the period June 2000-March 2002. *Id.* at 432, 438.[10] Oregon residents in the latter period were "approximately twice as likely to be reported to be in moderate or severe pain or distress during the last week of their lives." *Id.* at 436.[11]

Assisted suicide has also increasingly become a substitute for treating or even evaluating problems such as depression, as suggested by the fact that in Oregon only 14% of those dying from a lethal overdose in 2001 had received any referral for psychiatric evaluation (compared to 29% for the preceding three years). Oregon Department of Human Services, Fourth Annual Report on Oregon's Death with Dignity Act 16 (Feb. 6, 2002). By 2003 and 2004, the last years for which statistics are available, the percentage of Oregon patients referred for psychiatric evaluation had dropped to 5 percent. Oregon Department of Human Services, Sixth Annual Report on Oregon's Death with Dignity Act 23 (March 10, 2004), and Seventh Annual Report on Oregon's Death with Dignity Act 24 (March 10, 2005).[12]

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[10]In Oregon, being female and young "were significantly associated with greater reported pain or distress," *id.* at 436, reflecting the New York State Task Force's prediction that legalization of physician-assisted suicide would put certain classes of people at greater risk. *See* discussion *supra* at 14-15.

[11]There is also evidence that the use of morphine for dying patients in Oregon has not kept pace with the national increase in morphine use. Susan W. Tolle, M.D., *et al.*, *Trends in Opioid Use Over Time: 1997 to 1999*, 7 J. of Palliative Med. 39 (2004) (finding that inpatient morphine use in Oregon "did not increase significantly for dying patients from 1997 to 1999") (quoting the abstract).

[12]Accessible at http://egov.oregon.gov/DHS/ph/pas/index.shtml (visited

On the other hand, jurisdictions that recognize a distinction between pain management and assisted suicide, and prohibit the latter, see positive effects on the use of drugs to relieve pain. Between 1992 and 2004, at least 12 states enacted new laws that ban intentionally assisting suicide, or that strengthen or clarify existing bans, with statutory language affirming the use of medications to control pain even when this may unintentionally increase the risk of death.[13] Data from the Drug Enforcement Administration on morphine use for these 12 states show that per capita use of morphine subsequently increased in every case, sometimes dramatically.[14] In these 12 states, the average increase in the use of morphine, the controlled substance most commonly used to alleviate pain in terminally ill patients, was 45 percent; in three states, morphine use doubled.

April 13, 2005).

[13] Iowa Code §§ 707A.1 to 707A.3; Kan. Stat. Ann. §§ 21-3406, 60-4403; Ky. Rev. Stat. Ann. §§ 216.302 to 216.308; La. Rev. Stat. Ann. § 14:32.12; Md. Ann. Code art. 27, § 416, repealed and reenacted without substantive change, Md. Code Crim. Law §§ 3-101 to 3-104; Ohio Rev. Code §§ 3795.01 to 3795.03; Okla. Stat. tit. 63, §§ 3141.1 to 3141.8; R.I. Gen. Laws §§ 11-60-1 to 11-60-5; S.C. Code Ann. § 16-3-1090; S.D. Codified Laws §§ 22-16-37.1 to 22-16-37.7, transferred to Chapter 34-12D by 2005 S.D. Laws, ch. 120 (SB 43); Tenn. Code Ann. § 39-13-216; Va. Code Ann. § 8.01-622.1.

[14] Drug Enforcement Administration, U.S. Department of Justice, Statistics on Individual State Consumption of Morphine (on file with the Subcommittee on the Constitution of the House Committee on the Judiciary). *See also* HANDBOOK OF PAIN RELIEF IN OLDER ADULTS: AN EVIDENCE-BASED APPROACH 193 (F. Michael Gloth, M.D., ed., 2004) (noting that "in every state that had passed such legislation [distinguishing between relieving pain and assisting suicide, and prohibiting the latter], there was an increase in the legitimate prescription of opioids and other strong medications used for pain control").

Data from the 12 states,[15] showing per capita use of morphine (expressed in grams per 100,000 people) in the years before and after enactment of a law against assisted suicide, are as follows:

Iowa – passed law in 1996 (took effect July 1996)

1995 – 935 g – 30th among states
1996 – 1,221 – 28th
1997 – 2,207 – 26th
1998 – 2,029 – 38th

Percentage change in morphine use: +136%.[16]

Kansas – passed law in 1998 (took effect July 1998)

1997 – 2,047 g – 35th
1998 – 2,016 – 39th
1999 – 2,179 – 32nd
2000 – 2,600 – 27th

Percentage change in morphine use: +6%.

Kentucky - passed law in 1994 (took effect July 1994)

1993 – 1,388 g – 11th
1994 – 1,624 – 6th
1995 – 1,462 – 4th
1996 – 1,673 – 7th

Percentage change in morphine use: +5%.

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[15] *Id.*

[16] All percentage changes shown are from the year before, to the year after, the newly enacted legislation's effective date.

Louisiana – passed law in 1995 (took effect June 1995)

1994 – 843 g – 41st
1995 – 786 – 45th
1996 – 1,058 – 37th
1997 – 1,845 – 42nd

Percentage change in morphine use: +26%.

Maryland – passed law in 1999 (took effect October 1999)

1998 – 2,858 g – 16th
1999 – 2,990 – 15th
2000 – 3,233 – 14th

Percentage change in morphine use: +13%.

Ohio – passed law in 2002 (took effect March 2003)

2001 – 2,586 – 37th
2002 – 3,105 – 37th
2003 – 3,874 – 32nd
2004 – 4,822 – 26th

Percentage change in morphine use: +55%.

Oklahoma – passed law in 1998 (took effect November 1998)

1997 – 2,097 g – 31st
1998 – 2,186 – 30th
1999 – 2,137 – 34th
2000 – 2,624 – 26th

Percentage change in morphine use: +2%.

Rhode Island – passed law in 1996 (took effect July 1996)

1995 – 928 g – 33rd
1996 – 966 – 46th
1997 – 2,454 – 18th
1998 – 2,480 – 24th

Percentage change in morphine use: +164%.

South Carolina – passed law in 1998 (took effect June 1998)

1997 – 1,457 g – 51st
1998 – 1,625 – 49th
1999 – 1,659 – 49th
2000 – 2,055 – 45th

Percentage change in morphine use: +14%.

South Dakota – passed law in 1997 (took effect July 1997)

1996 – 978 g – 45th
1997 – 2,132 – 30th
1998 – 1,896 – 43rd
1999 – 1,880 – 43rd

Percentage change in morphine use: +94%.

Tennessee – passed law in 1993 (took effect July 1993)[17]

1992 – 1,180 g – 16th
1993 – 1,417 – 9th
1994 – 1,544 – 8th
1995 – 1,407 – 7th

Percentage change in morphine use: +31%.

Virginia – passed law in 1998 (took effect July 1998)

1997 – 2,007 g – 37th
1998 – 2,106 – 33rd
1999 – 2,401 – 27th
2000 – 2,687 – 28th

Percentage change in morphine use: +20%.

During the same period, 1992 to 2004, three other states passed laws against assisted suicide that did not include language affirming pain control.[18] Even in those three states, per capita use of morphine tended to stay about the same or to increase slightly. Morphine use rose by an average of 3 percent. This suggests that prohibiting assisted suicide generally does not have a "chilling effect" on legitimate pain control, but ideally should be accompanied by an explicit affirmation of the legitimacy of pain management (like the affirmations included in ASFRA and

[17]In 2004, Tennessee ranked highest among all states – 12,458 grams of morphine per 100,000 people. Second highest was Arizona (12,395 grams per 100,000 people), which also prohibits assisted suicide by statute. Ariz. Rev. Stat. § 13-1103.

[18]Ga. Code Ann. § 16-5-5; Ill. Comp. Stat. ch. 720, § 5/12-31; Mich. Comp. Laws § 750.329a.

the Attorney General's November 2001 directive).

The three states are as follows:

Georgia – passed law in 1994 (took effect July 1994)

1993 – 1,029 g – 28th among the states
1994 – 937 – g – 33rd
1995 – 838 – g – 39th
1996 – 1,030 g – 39th

Percentage change in morphine use (from year before enactment to year after): -19%.[19]

Illinois – passed law in 1993 (took effect January 1993)

1992 – 811 g – 40th among states
1993 – 872 – 39th
1994 – 880– 46th
1995 – 822 – 40th

Percentage change in morphine use: +9%.

Michigan – passed law in 1998 (took effect September 1998)

1997 – 2,251 – g – 24th
1998 – 2,540 – 23rd
1999 – 2,700 – 19th
2000 – 2,957 – 23rd

Percentage change in morphine use: +20%.

[19]A year later, morphine use returned to its 1993 level.

It would be a mistake to turn away from the import of this overwhelming evidence. The data clearly indicate that, if assisting terminally ill persons is our principal concern, removing barriers to effective administration of palliative care and raising barriers to assisted suicide work best. The Attorney General's decision promotes proper assistance to the terminally ill as reflected in the data presented here.

CONCLUSION

The Attorney General was correct in finding that assisted suicide is not a legitimate medical practice under the Controlled Substances Act, and in clearly distinguishing this practice from the use of controlled substances to manage pain. Accordingly, the decision of the Court of Appeals should be reversed and the injunction vacated.

Respectfully submitted,

Mark E. Chopko*
General Counsel
Michael F. Moses
Associate General Counsel
United States Conference
of Catholic Bishops
3211 Fourth St., N.E.
Washington, DC 20017
(202) 541-3300

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* Counsel of Record

(15)

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In The

Supreme Court of the United States

October Term, 2005

ALBERTO R. GONZALES,
Attorney General of the United States, *et al.*,
Petitioners,

v.

STATE OF OREGON, *et al.*,
Respondents.

On Writ of Certiorari
To The U.S. Court of Appeals
For The Ninth Circuit

BRIEF AMICUS CURIAE OF THE INTERNATIONAL TASK FORCE ON EUTHANASIA AND ASSISTED SUICIDE In Support of Petitioners

RITA L. MARKER, Esq.
Counsel of Record
1233 MARYLAND AVENUE
STEUBENVILLE, OH 43952
(740) 282-3810

ST IVES FINANCIAL/APPELLATE DIVISION, 1717 ARCH STREET PHILA., PA 19103 (215) 563-9000

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iv
INTEREST OF AMICUS CURIAE	1
SUMMARY OF ARGUMENT	2
ARGUMENT	3
I. The Ashcroft Directive does not criminalize assisted suicide, nullify Oregon's assisted suicide law or interfere with Oregon's ability to control the practice of medicine	3
A. Under the Ashcroft Directive, assisted suicide would remain legal in Oregon	4
B. Under the Ashcroft Directive, physicians may still prescribe assisted suicide	4
C. The Ashcroft Directive does not affect state control of medical practice in Oregon	9
II. The United States has never considered prescribing drugs to cause death to be a legitimate medical purpose, nor has it ever deemed drug-induced death for any patient to be in the public interest	10
A. The federal government has consistently viewed drug-induced death as a threat to public health	10
B. The CSA has never provided an exception for individuals with a terminal illness	11
C. Maintaining national standards pertaining to federally controlled substances is vital to prevent chaos and to protect public health and safety	13

TABLE OF CONTENTS

	Page
III. National and international standards of medical practice reject the use of drugs for the purpose of inducing a patient's death	14
A. Prescribing drugs for the purpose of inducing a patient's death does not reflect national medical standards	14
B. International standards of medical practice reject the provision of drugs for the purpose of induced death	17
1) *Assisted suicide and euthanasia are not considered legitimate medical practices in Australia where international standards of medical ethics are observed*	18
2) *In the Netherlands, where international standards of medical ethics are not observed, assisted suicide and euthanasia expanded to include drug-induced death for infants, children, and the mentally ill, followed by advocacy of the practices for healthy patients*	21
3) *In Belgium, which ignores international standards of medical ethics, legalization of euthanasia has rapidly led to infanticide and disregard for guidelines*	25
IV. Commercial distribution of federally controlled substances that are prescribed under the Oregon Death with Dignity Act is not wholly intrastate in nature	26
CONCLUSION	29

TABLE OF AUTHORITIES

Cases: **Page**

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) 3, 4, 7

United States v. Rutherford, 442 U.S. 544 (1970) . . . 12

Washington v. Glucksberg, 521 U.S. 702 (1997) 14

Statutes and Regulations:

21 U.S.C. 355 *et seq.* 12

21 U.S.C. 801 (1) 11

Or. Rev. Stat. §§127.800 *et seq.* (2003) 2

Or. Rev. Stat. §127.880 4

Or. Rev. Stat. §127.885(2) 9

Or. Rev. Stat. §§677.100 — 677.139 9

Or. Rev. Stat. §677.190(24) 9

Miscellaneous:

66 Fed. Reg. 56,607 (2001) 2, 9

Lisa Allison, *Nitschke to pick recruits for "suicide school,"* The Advertiser (Australia), Nov. 30, 2004 19

American Medical Association, the American Nurses Association, and the American Psychiatric Association, *et al*, Brief of *Amici Curiae* Supporting Petitioners at 3, *Vacco v. Quill* (No. 95-1858) (1996) 15

American Medical Association, *E-2.211 Physician-Assisted Suicide* (June 1994), updated June 1996, July 22, 2002 14

Amsterdam Forum, *Boundaries of euthanasia: Does unbearable suffering have to be linked to terminal illness?* Jan. 21, 2005 http://www2.rnw.nl/rnw/en/features/amsterdamforum/050122af 24

TABLE OF AUTHORITIES — *(Continued)*

Miscellaneous: **Page**

The Belgian Act on Euthanasia of May 28, 2002, 10 Eur. J. of Health L. 329 (2003) 25

The Belgian Act on Euthanasia of May 28, 2002, Chap. II, Sec. 3, §1. 25

Kerry Benefield, *State to weigh assisted suicide bill*, Press Democrat (Santa Rosa, CA), Apr.11, 2005. 17

Adrian Bradley, *Majority of doctors oppose euthanasia*, The Australian, Nov. 18, 1996 19

California Medical Association press release, *California Medical Association Opposes Physician-Assisted Suicide: Legalization Will Abuse Dying Patients' Rights and Dignity*, Apr. 21, 1999 http://www.cmanet.org/publicdoc.cfm 17

A. Chadly *et al*, *Suicide by Nitrous Oxide Poisoning*, 10 Am. J. Forensic Med. & Pathology 330 (1989) . . 8

Cheers Welcome Australia's "Dr Death", Chicago Tribune, Jan. 13, 2003 21

Compassion in Dying of Oregon, *Summary of Hastened Deaths*, attachment to IRS Form 990 for 2003, http://www.guidestar.org.Documents/2003/931/230/2003-931230393-1-9-pdf 16

Doctor aids first legal euthanasia act, 313 British Medical Journal 835 (1996) 19

Lawrence D. Egbert, MD, MPH, Message, "Perhaps helium better than barbiturates,"July 8, 2004 http://www.mailman.efn.org/ piper mail/right_to_die/2004-July/000172.html 8

First legal suicide reignites Australia euthanasia debate, American Medical News, Oct.14, 1996 . . 19

Brett Foley, *Euthanasia groups cool on suicide pill*, The Age (Australia), Aug. 3, 2001 20

Miscellaneous: **Page**

Kate Folmar, *Senate panel endorses assisted-suicide bill,* Contra Costa Times, Apr. 12, 2005. . . . . .16, 17

Diane Gianelli, *Oregon pharmacists wary of assisted-suicide measure,* Am. Med. News, Oct. 24/31, 1994. 28

CARLOS GOMEZ, REGULATING DEATH (1991).. . 22

Allan Hall, *Bill backs euthanasia for children,* The Scotsman, Sept. 9, 2004.. 26

Belinda Hickman, Katherine Glascott and Jody Scott, *Ethical dilemma,* The Australian, Sept. 27, 1996 19

Annick Hovine, *La mort á domicile, en kit spécial,* LaLibre, Apr. 15, 2005 http://www.lalibre.be/article.phtml?id=10&subid=90&art_id= 215636 26

Implications of Mercy, Time, March 5, 1973 . . . . . .21, 22

International Task Force, *Facts about Hemlock and Caring Friends* (2005) http://www.international taskforce.org/hemlockcf.htm 7, 8

Walter Lagerway, 3 Issues in Law and Medicine 429 (1988) 21

Joanne Lynn *et al, Public Policy: American Geriatrics Society on Physician-Assisted Suicide,* 45 Journal of the American Geriatrics Society, 489 (1997). . 15

Mail-Order Prescriptions Again Show Strongest Growth, 15 Drug Benefit Trends (3) 4 (2003) http:www.medscape.com/viewarticle/452209 27

RITA MARKER, DEADLY COMPASSION (2003). . . 23

Seth Mydans, *Assisted Suicide: Australia Faces a Grim Reality,* N. Y. Times, Feb. 2, 1997 . . . . . .19, 20

Nederlandse Jurisprudentie 1985, no. 106 (Alkmaar) 22

Nederlandse Jurisprudentie 1994, no. 656 (Assen) . . 22

Miscellaneous: **Page**

Nederlandse Jurisprudentie 1973, no. 183, District Court of Leeuwarden 21

Nightline (ABC television broadcast, Dec. 7, 1994) (transcript No. 3533) available in LEXIS/NEXIS. . 5, 6

Northern Territory Government (1995), *Rights of the Terminally Ill Act* 1995, Northern Territory of Australia, Darwin: Government Publisher 19

Margaret Oostveen, *Ik kan me goed voorstellen dat artsen stervenshulp niet melden,* NRL Handelsblad, Apr. 14, 2001 http://www.nrc.nl/W2/Nieuws/2001/04/14/Vp/01a.html (English translation available at http://www. international taskforce.org/holbors.htm). 24

Oregon Dept. of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act,* March 10, 2005, http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf 5

2 Oregon Health Law Manual 8-19, §8.23 (Oregon CLE 1997) 6, 7

Oregon Health Services, Center for Health Statistics, *Attending Physician's Compliance Form* http://egov.oregon.gov/DHS/ph/pas/docs/at1form.pdf. . . 28

Oregon Health Services, Center for Health Statistics, *Oregon Death with Dignity Act Attending Physician Interview Form* at 1 http://egov.oregon.gov/DHS/ph/pas/docs/mdintdat.pdf. 28, 29

Penal Code of the Netherlands, §§ 293 and 294 21

Maria M. Perotin, *Requirements for drugs via mail pits large companies against drugstore chains,* Fort Worth Star-Telegram, Feb. 27, 2005. 27

Miscellaneous: **Page**

Eric M. Peterson, *Notes & Comments: Doctoring Prescriptions: Federal Barriers to Combating Prescription Drug Fraud against On-Line Pharmacies,* 75 Wash. L. Rev. 1331 (2000) 27

Pretty v. United Kingdom, No. 2346/02, Eur. Ct. H.R. http://www.eher.coe.Int./Eng/Judgments. htm. . . 18

Veerle Provoost, *et al, Medical end-of-life-decisions in neonates and infants in Flanders,* 365 Lancet 1315 (2005) 26

Public Radio International and KCRW (Santa Monica, CA) *To the Point: Challenge to Oregon's Assisted Suicide Law* (February 23, 2005), transcript of Tape 1 16

Andis Robeznieks, *HMO query reignites assisted-suicide controversy,* American Medical News, Sept. 9, 2002. . . . . .15, 16

Andis Robeznieks, *Oregon sees fewer numbers of physician-assisted suicides,* American Medical News, April 4, 2005. 16

Christopher Rowland, *The Pharmacist is In: Chains Promote Personal Touch to Keep Edge over Mail-order Firms,* Boston Globe, Nov. 10, 2003 27

Sénat de Belgique, "Proposition de loi modifiant la loi du 28 mai 2002 relative à l'euthanasie," July 7, 2004 http://www.senate.be/wwwcgi/get_pdf?50332915 25

Tony Sheldon, *Dutch euthanasia law should apply to patients 'suffering through living,' report says,* 330 Brit. Med. J. 61 (2005). 24

Tony Sheldon, *Killing or caring?* 330 Brit. Med. J. 560 (2005). 25

Miscellaneous: **Page**

Lois Snyder and Daniel P. Sulmasy, *Position Paper: Physician-Assisted Suicide,* 135 Annals of Internal Medicine 209 (2001). 14

Toby Sterling, *Lifelong suffering can be valid reason for euthanasia, Dutch study finds,* Associated Press, Dec.16, 2004, available in LEXIS/NEXIS 24

Annette Street and David W. Kissane, *Dispensing Death, Desiring Death: An Exploration of Medical Roles and Patient Motivation during the Period of Legalized Euthanasia in Australia,* 40 OMEGA 234 (1999-2000) 19

Suicide kit goes on the Internet, The Mercury (Hobart, Australia), Oct. 21, 1996. 20

TABER'S CYCLOPEDIC MEDICAL DICTIONARY (19th ed. 2001). 5

Bob Tedeschi, *Want to Be an Online Drugstore? Take a Number,* N.Y. Times, Feb. 2, 1999 27

The Termination of Life on Request and Assisted Suicide (Review Procedure) Act http://www.minbuza.nl/default.asp?CMS_TCP=tcpAsset&id=CA83D9494B444D268938017F2330E54E 23

Tijdschrift voor Gezondheidsrecht 1992, no. 19 (Amelo) 22

U.S. Dept. of Justice Drug Enforcement Administration, *Pharmacist's Manual* http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/phar_content.htm 27

U.S. Public Health Service, *The Surgeon General's Call to Action to Prevent Suicide* (1999) 11

Eduard Verhagen and Pieter J. J. Sauer, *The Groningen Protocol — Euthanasia in Severely Ill Newborns,* 352 New Eng. J. Med. 959 (2005) . . . 25

Miscellaneous: **Page**

World Medical Association, *The World Medical Association Resolution on Euthanasia,* (2002) http://www.wma.net/e/policy/e13b.htm 17, 18

INTEREST OF AMICUS CURIAE

Amicus curiae, the International Task Force on Euthanasia and Assisted Suicide (ITF),[1] is an international leader in the debate over assisted suicide and euthanasia. ITF is the operating name of the Family Living Council, a non-profit corporation formed in 1976 to provide education related to issues impacting on the family. It addresses legal and public policy issues related to death and dying, health care delivery and pain control, the rights of the terminally ill, the chronically ill, the elderly, persons with disabilities and the impact of such issues on individuals and families.

The ITF has particular expertise in analyzing the practical implications and specific information related to both Attorney General Ashcroft's Directive and the Oregon Death with Dignity Act (ODWDA). This *amicus* brief will be of particular assistance to the Court since it demonstrates that the ODWDA may be carried out without the use of federally controlled substances, which is relevant to the fact that the Ashcroft Directive does not nullify Oregon's law but, instead, affirms the role of the federal government in interpreting its own regulations. Furthermore, it illustrates the fact that prescribing drugs for the purpose of inducing death is not in accordance with a standard of medical practice generally recognized and accepted nationally or internationally. Finally, it clarifies the interstate nature of activities under the ODWDA, which is relevant to maintaining a national standard for dispensing federally controlled substances.

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[1] Letters of consent for the filing of this brief have been filed with the Clerk. Counsel for a party did not author this brief in whole or in part and no person or entity other than *amicus curiae* has made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

This case is not about whether the State of Oregon may permit the practice of assisted suicide within its borders. It is about Oregon's attempt to determine the manner in which a federal registration to prescribe federally controlled substances may be used. The Oregon Death with Dignity Act (ODWDA) gives Oregon physicians the right to "prescribe medication" to induce death. Or. Rev. Stat. §§ 127.800 *et seq.* (2003). However, the ODWDA does not specify the type of drugs for that purpose.

While all federally controlled substances are prescription drugs, not all prescription drugs are federally controlled substances. The Directive issued by Attorney General Ashcroft was an interpretive rule dealing solely with whether using a federal registration to prescribe federally controlled substances to cause drug-induced death serves a "legitimate medical purpose" under DEA regulations. 66 Fed. Reg. 56,607 (2001). Under the Directive, Oregon physicians are still free to prescribe drugs that are not federally controlled.

National standards of medical practice reject the use of drugs for the purpose of inducing death. Likewise, international standards of medical practice reject the use of drugs for the purpose of inducing death. Yet, Oregon seeks to exempt itself from a uniform national standard. It seeks to substitute a state-determined interpretation of "legitimate medical purpose" for the use of federal registrations. Under such an interpretation, each state could determine the use of federally controlled substances, potentially resulting in fifty different sets of accepted purposes.

The use of federally controlled substances for assisted suicide does not affect only the state of Oregon. Distribution of federally controlled substances for assisted suicide cannot be confined within Oregon's borders since prescriptions can be filled through out-of-state mail order prescription services.

ARGUMENT

I. The Ashcroft Directive does not criminalize assisted suicide, nullify Oregon's assisted suicide law or interfere with Oregon's ability to control the practice of medicine.

The Ninth Circuit Court of Appeals erred when its majority asserted, "By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders..." *Oregon v. Ashcroft,* 368 F.3d 1118, 1124 (9th Cir. 2004). The Ashcroft Directive does not criminalize assisted suicide nor does it interfere with Oregon's regulation of medical care within its borders.

Congress granted authority to the Attorney General to carry out the Controlled Substances Act (CSA) and Drug Enforcement Administration (DEA) regulations that implement the CSA, including 21 C.F.R. § 1306.04 (a).

The Ashcroft Directive does not address the matter of whether assisted suicide may be considered a "legitimate medical *practice*" under Oregon law. It deals solely with whether using a federal registration to prescribe federally controlled substances to cause drug-induced death serves a "legitimate medical *purpose*" under DEA regulations.

If the Ashcroft Directive is implemented, and if a physician chooses to prescribe federally controlled substances for assisted suicide, administrative proceedings could be instituted. The outcome of those proceedings would determine whether the physician's federal registration is retained, revoked or suspended. No matter what the outcome of those administrative proceedings, the physician would still be able to lawfully prescribe non-federally controlled drugs and would still be able to practice medicine in Oregon. Furthermore, the physician would still be able to engage in assisted suicide under Oregon's law.

A. Under the Ashcroft Directive assisted suicide would remain legal in Oregon.

The Ninth Circuit's ruling erroneously stated that "Oregon's Death with Dignity Act authorizes physicians to prescribe lethal doses of controlled substances to terminally ill Oregon residents...." *Oregon v. Ashcroft*, 368 F.3d 1118, 1122. The ODWDA permits physicians to "prescribe medication," but does not define "medication." It does not authorize a particular method of inducing death other than precluding the use of a lethal injection, mercy killing or active euthanasia. Or. Rev. Stat. 127.880 (2003). Certainly, it does not specifically authorize physicians to prescribe lethal doses of controlled substances. Passage of the ODWDA approved the act of physician-assisted suicide. However, the ODWDA does not specify the *means* by which the act is to be accomplished. Nothing in the ODWDA limits "medication" to a federally controlled substance.

The Ninth Circuit also misspoke when it stated, "By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders...." *Oregon v. Ashcroft*, 368 F.3d 1118, 1124 (9th Cir. 2004).

The Ashcroft Directive does not prevent physicians from engaging in the *practice* of physician-assisted suicide under the ODWDA. Physicians may still write prescriptions for medication for the purpose of enabling patients to commit suicide. The Ashcroft Directive only addresses the *means*, by stating that practitioners may not use their federal registrations to prescribe federally controlled substances for the purpose of causing drug-induced deaths.

B. Under the Ashcroft Directive, physicians may still prescribe assisted suicide.

Although all federally controlled substances are prescription drugs, not all prescription medications are federally controlled substances. A federal registration is

only required to dispense prescription medications that are federally controlled substances. The Ashcroft Directive applies only to those prescription drugs for which a federally issued license is necessary and only to those drugs when they are prescribed for the purpose of enabling a patient to commit suicide.

Despite the fact that barbiturates (sleeping pills) taken by mouth account for 204 of the 208 deaths reported in the first seven years during which the ODWDA has been in effect (Oregon Dept. of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act*, March 10, 2005, http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf at 24, Table 4), the ODWDA does not limit the means of assisted-suicide deaths to oral medication.

While it is not the intent of *amicus* to provide "how to" instructions for assisted suicide, the discussion below is necessary to illustrate the full meaning of "medication" and the fact that assisted suicide can be carried out under the ODWDA without using federally controlled substances.

The ODWDA refers to a prescription for "medication" but does not define the term. However, accepted definitions of medication include: "medicinal substance, a drug, and treatment with remedies." TABER'S CYCLOPEDIC MEDICAL DICTIONARY 1017 (19th ed. 2001). "Remedy," which falls within the meaning of "medication" is defined as "anything that relieves or cures a disease." *Id.* at 1776.

Shortly after passage of the ODWDA in 1994, Peter A. Goodwin, MD, of the Oregon Health Sciences University, who was one of the authors of the ODWDA, appeared on ABC's *Nightline* to discuss the ODWDA. He explained that no route of administration of lethal medication would be excluded under the ODWDA "as long as the patient had full responsibility."[2]

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[2] Referring to a device in which a patient pushes a lever that activates the flow of a substance (similar to that which had been used by Jack Kevorkian to deliver carbon monoxide or another substance), Dr.

Thus, a prescription of "medication" as permitted under the ODWDA could encompass routes other than oral and substances other than barbiturates.

The fact that the ODWDA does not preclude varied routes of administration was also noted in a 1997 Oregon State Bar Association publication:

> An attending physician may write a prescription for "medication to enable a qualified patient to end his or her life in a humane and dignified manner." Or. Rev. Stat. §127.815(9) [sic]. The choice of drug, or drugs, is left to the discretion of the physician as a medical practice decision. 2 Oregon Health Law Manual 8-19, §8.23, Oregon CLE 1997.
>
> The *route of administration is also discretionary*, except that the Act expressly prohibits "lethal injection." Or. Rev. Stat. §127.880. It appears that other routes of administration — such as oral ingestion, rectal suppository. or transdermal absorption — would fall within the Act. *Id.* (emphasis added).

The publication goes on to ask and answer a query:

> Would a delivery method such as inhalation be eligible for immunity, since the Act does not expressly mention "devices," and some sort of delivery system would be needed for an inhaled gas? Interpretation may also be needed to clarify whether intravenous equipment, such as might be in place already for the treatment of pain and dehydration, may be used by the patient to deliver a slow infusion of medication. One might reasonably interpret a prescription for an "infusion" as distinct from an "injection," and therefore be within the scope of

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Goodwin stated that "if the patient had a gadget similar to that that Dr. Kevorkian used and wanted to do it that way, it's my belief that that would not be excluded as long as the patient had full responsibility." *Nightline* (ABC television broadcast, Dec. 7, 1994) (transcript No. 3533) available in LEXIS/NEXIS.

> the Act. *Because the goal of the Act is to regulate voluntary self-administration, the critical question is whether the medication, by whatever route, is self-administered. Id.* (emphasis added).

It seems highly probable that devices would be permitted under the ODWDA since a device is a "remedy" and does fall within the definition of "medication." Furthermore, prescriptions are frequently written for devices. For example, it is customary for physicians to write prescriptions for a specific type of dental appliance — known as a Mandibular Protruding Device (MPD) — as a remedy for sleep apnea.

Similarly, a device that could be used to enable a patient to end his or her life could be prescribed under the ODWDA. A physician could write a prescription for the type of assisted suicide appliance made from plastic tubing to be used with substances that are not federally controlled substances. Alternatively, a physician could merely direct the patient about how he or she might obtain the devices that are well known, widely advertised and widely distributed by assisted suicide proponents.

The Ninth Circuit inappropriately ventured into determining what it believed to be the optimal way to induce patients' deaths when the majority opined that "it is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives." *Oregon v. Ashcroft,* 368 F.3d 1118, 1123 (9th Cir. 2004).

It is interesting to note that, among those who have had actual experience in facilitating patients' deaths, there is actually some question about the merits of barbiturates.

For a number of years, the Hemlock Society (now known as Compassion and Choices) has operated a program called "Caring Friends" which provides how-to-commit-suicide information and in-person support to individuals as they die. *See:* International Task Force on Euthanasia

and Assisted Suicide, *Facts about Hemlock and Caring Friends* (2005) at http://www.internationataskforce.org/hemlockcf.htm.

Lawrence D. Egbert, MD, MPH, who acknowledges being present at about fifty deaths as a Caring Friends volunteer, has suggested that "helium is a better way to do a hastened death than barbiturates." Message from Lawrence D. Egbert, MD, MPH, "Perhaps helium better than barbiturates," (July 8, 2004) available at http://www.mailman.efn.org/pipermail/right_to_die/2004-July/000172.html, last accessed April 25, 2005.

An additional method of inducing a patient's death includes the use nitrous oxide. It has been used for suicide,[3] either alone or in combination with tricyclic antidepressants (which cause sedation). Another means could include the infusion of a massive overdose of insulin.

Accordingly, self-administration of "medication" under the ODWDA, can occur orally, by application of a patch, insertion of a suppository, activation of a device and/or inhalation of a substance.

While *amicus* believes that permitting assisted suicide in policy or in law is tragic for patients, dangerous for society and bad public policy, this case is not about overturning Oregon's law permitting assisted suicide. As discussed and illustrated above, implementation of the Ashcroft Directive does not nullify the ODWDA, nor does it prevent assisted suicide deaths under the Act.

[3] The use of nitrous oxide for suicide has been described in medical literature. *See, e.g.*, A. Chadly, B. Marc, D. Barres, M. Durigon, *Suicide by Nitrous Oxide Poisoning*, 10 Am. J. Forensic Med. & Pathology 330 (1989).

C. The Ashcroft Directive does not affect state control of medical practice in Oregon.

States regulate the practice of medicine. States issue medical licenses. Only states may revoke physicians' licenses to practice medicine.

The Attorney General, under the authority granted by the CSA, controls the dispensing of federally controlled substances. It is the Attorney General who registers physicians to prescribe federally controlled substances and it is the Attorney General who may suspend or revoke such registrations, in accordance with administrative procedures.

Physicians in Oregon are not required to have a federal registration to practice medicine. Without a federal registration, physicians may diagnose and treat patients. They may perform surgery. They may prescribe any of the thousands of medication that are not federally controlled substances.[4]

If the Ashcroft Directive is implemented, the conduct of a physician who prescribes federally controlled substances to assist suicide "*may* render his registration...inconsistent with the public interest and therefore subject to *possible* suspension or revocation under 21 U.S.C. §824(a)(4)." 66 Fed. Reg. 56,607 (2001) (emphasis added). Prescribing or providing medications for assisted suicide that are not controlled substances would not subject a practitioner's registration to any risk of suspension or revocation.

[4] For qualifications and licensing procedures for physicians, see Or. Rev. Stat. §§ 677.100 – 677.139. Although Oregon law provides that the Board of Medical Examiners *may* suspend or revoke a physician's license to practice medicine if the physician violates the federal CSA Or. Rev. Stat. §677.190 (24), the ODWDA prevents the state from taking such action against a physician for actions in compliance with the ODWDA. Or. Rev. Stat. §127.885 (2).

II. The United States has never considered prescribing drugs to cause death to be a legitimate medical purpose, nor has it ever deemed drug-induced death for any patient to be in the public interest.

A. The federal government has consistently viewed drug-induced death as a threat to public health.

Opponents of the Ashcroft Directive have asserted that, since the CSA does not explicitly state that assisted suicide is not a legitimate medical practice, Congress did not intend to prevent a practitioner from prescribing federally controlled substances for that purpose.

On the contrary. While, in 1984, no one envisioned that any medical professional would seriously claim that assisting suicide was a "legitimate medical practice," there was great concern about the serious threat that drug-induced deaths posed to public health and safety. When Congress amended the CSA in that year, it did so to strengthen the ability of the Attorney General to deny, suspend or revoke registrations of practitioners who dispensed federally controlled substances in a way that threatened public health and safety and to give the Attorney General the authority to act in cases where a state was either unable or unwilling to intervene.

At that time, supporters of amending the CSA based the legal change on the need to expand the Attorney General's authority so that the most serious threat to public health and safety — the frequency with which prescription drugs were involved in drug-induced deaths — could be addressed.

Indeed, common sense dictates that the basis for control of certain drugs is the prevention of threats to health and life. Throughout the history of the nation, intentionally participating in causing or enabling drug-induced death has never been considered a legitimate medical practice.

Furthermore, suicide has never been viewed as a treatment or therapy for any medical condition.

As recently as 1999, David Satcher, MD, then Surgeon General of the United States, declared, "Suicide is a serious public health problem." U.S. Public Health Service, *The Surgeon General's Call to Action to Prevent Suicide* (1999) at 1. He noted that suicide was the ninth leading cause of mortality in the United States, accounting for nearly 31,000 deaths per year, a number that was more than 50 percent higher than the number of homicides for the same year. *Id.*

Surgeon General Satcher urged implementation of a comprehensive national strategy for suicide prevention as an important step in responding to the "the major public health problem of suicide in the United States." *Id.* at 16. He did not urge suicide prevention for all but the terminally ill.

B. The CSA has never provided an exception for individuals with a terminal illness.

When it passed the CSA, Congress found, "Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. §801 (1). Thus, the CSA grants exemptions to the overall prohibition on dispensing controlled substances so that those substances may be dispensed for useful and legitimate medical purposes that are needed to maintain the health and general welfare of the American people.

Suicide — including suicide by intentional overdose of federally controlled substances — has never been considered an act that maintains "health and general welfare."

Those who oppose the Ashcroft Directive would have this Court believe that there is an implied exception to the CSA, permitting prescriptions for federally controlled substances to assist suicides of terminally ill patients. There is, however, no basis for such an exception.

Nowhere is there any evidence that Congress intended protections related to drugs to apply only to persons suffering from curable diseases. In *Rutherford*, the Court noted that "the concept of safety under §201 (p) is not without meaning for terminal patients." *United States v. Rutherford*, 442 U.S. 544, 552, 555 (1970). In its discussion of the Food and Drug Administration's (FDA) approval of drugs for use by the public, this Court declared, "For the terminally ill, *as for anyone else*, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *Id.* at 555-556 (emphasis added).

If the FDA will not approve a drug for use if its *potential* for inducing death is not offset by the possibility of therapeutic benefit, it is preposterous to think the Attorney General should be compelled to authorize prescribing controlled substances for the specific *purpose* of inducing death.

Just as the legislative history and consistent administrative interpretation of the Federal Food, Drug, and Cosmetic Act (FDCA), (21 U.S.C. 355 *et seq.*) gave no implicit exception to the terms "safe" and "effective" for drugs used by the terminally ill, the CSA does not imply any exception to the meaning of "public health and safety" for those who are terminally ill.

The concept of "safety" applies equally to all patients under the FDCA, including terminally ill patients. So, also, the meaning of "public health and safety" is equally applicable to all patients – young and old, rich and poor, temporarily ill, chronically ill, and terminally ill – under the CSA.

Moreover, if prescribing federally controlled substances for the purpose of causing drug-induced death for terminally ill patients were to be considered a legitimate medical purpose, the Attorney General would be compelled to consider such prescribing a legitimate medical purpose for

any and all other patients if a state so decides since the exception to the CSA would be based on a state's right to decide how a federal registration may be used.

C. Maintaining national standards pertaining to federally controlled substances is vital to prevent chaos and to protect public health and safety.

The Ninth Circuit's decision radically undermines the Federal Government's ability to enforce a uniform national standard related to federal registrations and federally controlled substances. It renders the federal government powerless to interpret its own regulations.

This has broad implications. Indeed, if Oregon has the right to unilaterally determine what constitutes a legitimate medical purpose under federal regulations promulgated under the CSA, then each and every state has similar authority. Absent uniform enforcement of the CSA, chaos will ensue.

The use of a federal registration to prescribe controlled substances would be subject to widely varied and constantly changing state determinations. One state could choose to permit physicians to use their federal registrations to prescribe federally controlled substances to terminally ill people for the purpose of suicide. Another could decide that such registrations could be used to prescribe federally controlled substances for recreational purposes. Yet another may choose to do both of the preceding while another may choose to do neither. Essentially, any state could prevent federal officials from enforcing the CSA within its borders. Although the CSA and its relevant regulations are federal, enforcement of federally controlled substances would be virtually impossible.

Unless the Ninth Circuit's decision is overturned, the power to regulate the medical uses of federally controlled substances will rest with each state, potentially leading to fifty different interpretations of what constitutes a proper

medical purpose for prescribing federally controlled substances. This would compel the federal government to cede all authority for interpreting and regulating controlled substances to the individual states and would result in total disintegration of a national drug policy as it relates to prescriptions for narcotics.

III. National and international standards of medical practice reject the use of drugs for the purpose of inducing a patient's death.

A. Prescribing drugs for the purpose of inducing a patient's death does not reflect national medical standards.

As this Court has previously noted, the American Medical Association, in its Code of Ethics, condemns physician-assisted suicide as an act that is incompatible with the physician's role as a healer. *Washington v. Glucksberg,* 521 U.S. 702, 731 (1997).

That position, explicitly stating that "allowing physicians to participate in assisted suicide would cause more harm than good" and that "physician assisted suicide is fundamentally incompatible with the physician's role as healer" remains unchanged. American Medical Association, *E-2.211 Physician-Assisted Suicide* (June 1994), based on the reports *Decisions Near the End of Life* (adopted June 1991) and *Physician-Assisted Suicide* (adopted December 1993), (JAMA 1992:267:2229-2233); updated June 1996, July 22, 2002.

The American College of Physicians-American Society of Internal Medicine opposes physician-assisted suicide, stating that it "raises serious ethical and other concerns" and that it would "endanger the value our society places on life, especially the lives of disabled, incompetent, and vulnerable individuals." Lois Snyder and Daniel P. Sulmasy, *Position Paper: Physician-Assisted Suicide,* 135 Annals of Internal Medicine 209 (2001).

The American Geriatrics Society has noted that limits on physician-assisted suicide would be difficult to maintain, that problems in carrying it out would be legion and that, "by collaborating in causing early deaths, when continuing to live has been made so difficult, geriatricians would become complicit in a social policy which effectively conserves community resources by eliminating those who need services." Joanne Lynn *et al, Public Policy: American Geriatrics Society on Physician-Assisted Suicide,* 45 Journal of the American Geriatrics Society, 489, 490-491 (1997).

Furthermore, in November 1996, 46 national specialty and state medical societies filed a brief with this Court stating that, although it might appear compassionate to intentionally cause death, "institutionalizing physician-assisted suicide as a medical treatment would put many more patients at serious risk for unwanted and unnecessary death." Brief of *Amici Curiae* American Medical Association, the American Nurses Association, and the American Psychiatric Association, *et al* Supporting Petitioners at 3, *Vacco v. Quill* (No. 95-1858) (1996).

Clearly, prescribing federally controlled substances for the purpose of inducing death does not reflect national medical standards.

Even in Oregon, physicians are reluctant to become involved in assisted suicide. This has led one managed care corporation to solicit physicians to become assisted-suicide providers.

On August 6, 2002, Robert Richardson, MD, Administrator of Oregon's Kaiser Permanente, sent an e-mail to doctors affiliated with Kaiser, asking them to contact him if they were willing to act as the "attending physician" for patients requesting assisted suicide. According to the message, the HMO needed more physicians because, "Recently our ethics service had a situation where no attending MD could be found to assist an eligible member in implementing the law for three weeks...." Andis Robeznieks,

HMO query reignites assisted-suicide controversy, American Medical News, Sept. 9, 2002.

The lack of willing physicians has resulted in assisted-suicide advocacy groups such as the Hemlock Society and Compassion in Dying, (now combined under the name "Compassion and Choices") and physician activists being the main facilitators of assisted suicide in Oregon. According to Compassion in Dying, the group was involved in 79 percent of Oregon assisted-suicide deaths in 2003. Compassion in Dying of Oregon, *Summary of Hastened Deaths,* attachment to IRS Form 990 for 2003, available at http://www.guidestar.org.Documents/2003/931/230/2003-931230393-1-9-pdf.

Assisted-suicide activist Peter Rasmussen, MD, has acknowledged writing assisted-suicide prescriptions numbering in the double digits. Public Radio International and KCRW (Santa Monica, CA) *To the Point: Challenge to Oregon's Assisted Suicide Law* (Feb. 23, 2005), transcript of Tape 1, p. 5. In addition, Dr. Rasmussen admits that he prescribes assisted suicide for patients he has not treated and with whom he has spent as little as three hours, either in person or by phone, before writing the prescription. Andis Robeznieks, *Oregon sees fewer numbers of physician-assisted suicides,* American Medical News, Apr, 4, 2005.

In states where laws similar to Oregon's assisted-suicide law have been proposed, state medical organizations have failed to support the measures. Most recently, during an April 2005 Assembly Judiciary Committee hearing regarding the proposed California "Compassionate Choice Act" (A.B. 654), a measure virtually identical to Oregon's assisted-suicide law, Michael Sexton, MD, president of the California Medical Association (CMA), spoke on behalf of the organization. Explaining that a doctor is responsible "to, at all times, act in the best interests of the patient," Dr. Sexton said the assisted-suicide bill "puts physicians in a position where they're not acting in the patient's best interest." Kate

Folmar, *Senate panel endorses assisted-suicide bill,* Contra Costa Times, Apr. 12, 2005.

The CMA's opposition to A.B. 654 is consistent with the group's strong position against 1992 and 1999 attempts to legalize assisted suicide in California. California Medical Association press release, *California Medical Association Opposes Physician-Assisted Suicide: Legalization Will Abuse Dying Patients' Rights and Dignity,* Apr. 21, 1999, available at http://www.cmanet.org/ publicdoc.cfm. That policy was reaffirmed at the CMA's annual meeting in March 2005. Kerry Benefield, *State to weigh assisted suicide bill,* Press Democrat (Santa Rosa, CA), Apr.11, 2005.

Assisted suicide is a violation of acceptable national medical standards in the United States, and it is also considered unethical in most of the world.

B. International standards of medical practice reject the provision of drugs for the purpose of induced death.

Throughout most of the world, assisted suicide and euthanasia are considered profound violations of medical ethics.

The World Medical Association (WMA), with members representing medical associations (including the American Medical Association) from eighty-two countries, has adopted strong resolutions condemning both euthanasia and assisted suicide and urging all national medical associations and physicians to refrain from participating even if national law allows or decriminalizes the practices:

> Euthanasia, that is the act of deliberately ending the life of a patient, even at the patient's own request or at the request of close relatives, is unethical. This does not prevent the physician from respecting the desire of a patient to allow the natural process of death to follow its course in the terminal phase of sickness. World Medical Association, *The World Medical Association Resolution*

on Euthanasia, (adopted by the 38th WMA Assembly, Madrid, Spain, October 1987, reaffirmed by WMA General Assembly, Washington, 2002, May 2001, 20.3/2001) available at http://www.wma.net/e/policy/e13b.htm (last accessed March 15, 2005).

Physician-assisted suicide, like euthanasia is unethical and must be condemned by the medical profession. Where the assistance of the physician is intentionally and deliberately directed at enabling an individual to end his or her own life, the physician acts unethically. However, the right to decline medical treatment is a basic right of the patient and the physician does not act unethically even if respecting such a wish results in the death of the patient. World Medical Association, *The World Medical Association Resolution on Euthanasia* (adopted by the 44th WMA Assembly, Marbella, Spain, September 1992, reaffirmed by WMA General Assembly, Washington, 2002, May 2001, 20.3/2001) available at http://www.wma.net/e/policy/e13b.htm (last accessed March 15, 2005).

When it decided an assisted-suicide case, the European Court of Human Rights found that its policies "did not confer any claim on an individual to require a State to permit or facilitate his or her death." *Pretty v. United Kingdom,* No. 2346/02, Eur. Ct. H.R. available at http:// www. eher.coe.Int. / Eng/ Judgments.htm.

In addition to the state of Oregon and in spite of the nearly universal rejection of assisted suicide and euthanasia, only three countries (Australia, which later repealed its law, the Netherlands and Belgium), have passed laws permitting assisted suicide and euthanasia.

1) *Assisted suicide and euthanasia are not considered legitimate medical practices in Australia where international standards of medical ethics are observed.*

In 1995, with the passage of the "Rights of the Terminally Ill (ROTI) Act," Australia's Northern Territory

became the only jurisdiction in the world with both legalized assisted suicide and euthanasia. Northern Territory Government (1995), *Rights of the Terminally Ill Act 1995,* Northern Territory of Australia, Darwin: Government Publisher. The law went into effect in July 1996, but was repealed on March 25, 1997. The Australian Medical Association opposed the Northern Territory legislation while it was in effect and continues to oppose both euthanasia and assisted suicide. *See, e.g.,* Belinda Hickman, Katherine Glascott and Jody Scott, *Ethical dilemma,* The Australian, Sept. 27, 1996; *Doctor aids first legal euthanasia act,* 313 Brit. Med. J. 835 (1996); Adrian Bradley, *Majority of doctors oppose euthanasia,* The Australian, Nov. 18, 1996; and Lisa Allison, *Nitschke to pick recruits for "suicide school,"* The Advertiser (Australia), Nov. 30, 2004 at 25.

During the eight months the law was in effect, four deaths occurred under its assisted-suicide provision. Dr. Philip Nitschke, a long-time activist and campaigner for assisted suicide and euthanasia, was listed as a certifying physician under the law and facilitated all four deaths. Annette Street and David W. Kissane, *Dispensing Death, Desiring Death: An Exploration of Medical Roles and Patient Motivation during the Period of Legalized Euthanasia in Australia,* 40 OMEGA 234, 237 (Table 1) (1999-2000). Before his involvement with assisted suicide, Nitschke had not been involved in caring for terminally ill people nor had he been a part of any medical or palliative care network in the Northern Territory. *Id.* at 238.

The method used to end the four patients' lives was a far cry from what would be considered an accepted medical procedure. It was appropriately described as "death-by-laptop." *First legal suicide reignites Australia euthanasia debate,* American Medical News, Oct.14 1996. To facilitate the deaths, Dr. Nitschke made house calls, carrying a suitcase that held his laptop computer, plastic tubing, and a pump-driven syringe filled with barbiturates. Seth Mydans,

Assisted Suicide: Australia Faces a Grim Reality, N. Y. Times, Feb. 2, 1997, at A3.

The computer was equipped with an interactive suicide software program. After the patient was hooked up to an intravenous line connected to the computer and the program was turned on, a series of three questions appeared on the computer screen to test the person's intent to commit suicide.

If the patient clicked "yes" in response to each question, a syringe driver and a sequential delivery of death-inducing drugs were activated. *Id.* The method meant that the doctor did not directly administer the fatal dose.

Even while the Northern Territory law was in effect, Dr. Nitschke was designing another death-inducing machine that would use carbon monoxide and an oxygen mask, thus eliminating the need for drugs. He said such a device would enable people to end their lives without needing someone to insert intravenous tubes and would be better for older people. "When people get too old and frail it can be very difficult to get access to veins and gas is a much easier way to go," he explained. *Suicide kit goes on the Internet,* The Mercury (Hobart, Australia), Oct. 21, 1996 at 12.

After repeal of the Northern Territory law, he stepped up his efforts to design the perfect assisted-suicide method. The Hemlock Society (now known as Compassion and Choices) provided tens of thousands of dollars for his various projects. Brett Foley, *Euthanasia groups cool on suicide pill,* The Age (Australia), Aug. 3, 2001. Also see: International Task Force, *Assisted Suicide: Not for Adults Only,* (2002) available at: http://www.international taskforce.org/noa.htm.

In December 2002, Dr. Nitschke unveiled the "COGen" machine, a more elaborate model of his earlier carbon monoxide and face mask method. *Id.* The device generates carbon monoxide delivered to the recipient through nasal

prongs. As the celebrity speaker at Hemlock's 13th Biennial Conference held in San Diego, he told a cheering audience, "You don't need a doctor! You can die without one! You can do it! You can do it yourself!" *Cheers Welcome Australia's "Dr Death,"* Chicago Tribune, Jan. 13, 2003.

The activities of Dr. Philip Nitschke highlight the non-medical nature of death by assisted suicide. His acknowledgment that a doctor is not needed underscores the fact that, although a physician may carry it out, assisted suicide is not a medical act. And, although drugs may be used in some assisted-suicide deaths, their use for assisted suicide constitutes a life-ending, not a medical, purpose.

2) *In the Netherlands, where international standards of medical ethics are not observed, assisted suicide and euthanasia expanded to include drug-induced death for infants, children, and the mentally ill, followed by advocacy of the practices for healthy patients.*

Euthanasia and assisted suicide have been widely practiced in the Netherlands for a number of years. However, they were against the law until 2002. Penal Code of the Netherlands, §§ 293 and 294. The Dutch situation between 1973 and 2002 stemmed from a series of court decisions and medical association guidelines that began with a 1973 District Court case. In that case, Dutch physician Geertruida Postma was convicted of the crime of euthanasia after she ended the life of her seriously ill mother. *Nederlandse Jurisprudentie* 1973, no. 183, District Court of Leeuwarden, 21 (Feb. 21, 1973); See translation in Walter Lagerway, 3 Issues in Law and Medicine 429, 439-42 (1988). The conditions under which the elderly woman died might have never come to the attention of authorities had it not been for Dr. Postma's insistence that her actions be made public. *Implications of Mercy,* Time, March 5, 1973, at 70.

The highly visible case became a rallying point for those seeking to change the law. Doctors in the province signed an

open letter to the Netherlands Minister of Justice stating that euthanasia was commonly practiced. *Id.*

Although it found Dr. Postma guilty of the crime of mercy killing that was punishable by imprisonment for a maximum of 12 years, the court imposed only a one-week suspended sentence and a one-week probation. The Dutch court relied heavily on expert testimony by the District's medical inspector who set forth certain conditions under which the average physician thought euthanasia should be considered acceptable. Those conditions[5] formed the basis for subsequent acceptance of euthanasia and assisted suicide in the Netherlands.

Other cases followed, initiated by physicians with the support of the Dutch Medical Association.[6] Each widened the boundaries and further liberalized the conditions under which euthanasia and assisted suicide would remain illegal, but not punishable. If the guidelines were followed, prosecution would not take place.

Dutch physicians have expressed certainty that there is no need for any real oversight of their activities. At a 1990

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[5] The guidelines required that the patient must be considered incurable (not necessarily terminal) and experiencing subjectively unbearable suffering, the request for termination of life should be in writing and there should be adequate consultation with other physicians before death could be induced. CARLOS GOMEZ, REGULATING DEATH, 30 (1991).

[6] Among the cases was one in which a woman died after requesting death due to advancing age and a physical condition that caused her to be dependent on others, thus leading to psychological suffering. (Alkmaar) *Nederlandse Jurisprudentie* 1985, no. 106. The case gave rise to the 1986 decision by the Hague Court of Appeals recognizing "psychic suffering" and "potential disfigurement of personality" as grounds for induced death. The court exonerated physicians who assisted in the suicide of a young woman with *anorexia nervosa*. (Amelo) *Tijdschrift voor Gezondheidsrecht* 1992, no. 19. Another exoneration took place in the case of a woman who was depressed over the death of her two children and the failure of her marriage. (Assen) *Nederlandse Jurisprudentie* 1994, no. 656.

right-to-die conference held in the Netherlands, Dr. H. S. Cohen, a Dutch general practitioner who has often carried out euthanasia, was asked if there was ever any abuse related to the practice of euthanasia. Cohen dismissed the possibility, saying that the Dutch medical establishment is of such high integrity that it is "not corruptible." RITA MARKER, DEADLY COMPASSION 142-143 (2003).

On April 10, 2001, the Dutch Parliament approved the "Termination of Life on Request and Assisted Suicide (Review Procedures) Act." It amended sections of the criminal code, specifically stating that the offenses of euthanasia and assisted suicide are not punishable if they have been "committed by a physician who has met the requirements of due care" that are described in the act and if they have informed the municipal "autopsist" in accordance with the Burial and Cremation Act. The Termination of Life on Request and Assisted Suicide (Review Procedure) Act, at http://www.minbuza.nl/default.asp?CMS_TCP=tcpAsset&id=CA83D9494B444D268938017F2330E54E.

The inclusion of "due care" requirements transformed the crimes of euthanasia and assisted suicide into medical treatments, just as physicians had advocated. Under the new law, minors between sixteen and eighteen may request that their lives be terminated and, although parents or guardians must be consulted, they have no authority to prevent the requested death. *Id.* Chapter II, Due Care Criterian, Section 2 (3). Children between the ages of twelve and sixteen may request euthanasia or assisted suicide but a parent or guardian must agree with the decision. *Id.* Section 2 (4).

The law recognizes the right of a physician to carry out euthanasia based on a written advance request for death of a currently incapacitated patient who is 16-years-old or older. *Id.* Section 2 (2). Although the person must be at least 16-years-old to be euthanized there is no requirement that one be at least that age when the request is put in writing.

Within days of the new law's passage, Dutch Health Minister Els Borst, who had guided the bill through parliament, said the government should consider introducing a suicide pill for patients who are healthy but are ready to die. Borst said this would be carefully regulated. Margaret Oostveen, *Ik kan me goed voorstellen dat artsen stervenshulp niet melden,* NRL Handelsblad, Apr. 14, 2001, available at: http://www.nrc.nl/W2/Nieuws/2001/ 04/14/Vp/ 01a.html (English translation available at http://www. international task force.org/holbors.htm). Three years later, the Royal Dutch Medical Association (KNMG) issued a report, known as the "Dijkhuis Commission Report."[7] It argued that the criteria in place for euthanasia under the current law were unhelpful in defining the limits of medical practice. Toby Sterling, *Lifelong suffering can be valid reason for euthanasia, Dutch study finds,* Associated Press, Dec.16, 2004, available in LEXIS/NEXIS. The report stated that the guidelines were "an illusion." Tony Sheldon, *Dutch euthanasia law should apply to patients 'suffering through living,' report says,* 330 Brit. Med.J. 61 (2005). It concluded that euthanasia should be allowed for virtually anyone who didn't want to live.

According to Dr. Rob Jonquiere of the Dutch Voluntary Euthanasia Society, the proposal addresses an "existential problem" outside of the medical domain but should, nevertheless, be adopted since it is within the context of ending unbearable suffering. Amsterdam Forum, *Boundaries of euthanasia: Does unbearable suffering have to be linked to terminal illness?* Jan. 21, 2005, available at http://www2.rnw.nl/rnw/en/features/amsterdam forum/ 050122af. The KNMG said it would "take the lead" in discussing how the issue confronts doctors in practice. Sterling, *supra.*

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[7] The full report of the Dijkhuis Commission is available, in Dutch, at http://knmg.artsennet.nl/uri/?uri=AMGATE_6059_100_TICH_ R144638358841695.

Three months later, the University Medical Centre Groningen, acknowledged that it had been euthananizing infants, not only in the case of terminally ill newborns but also in cases of children who had spina bifida and other disabilities. Tony Sheldon, *Killing or caring?* 330 Brit. Med. J. 560 (2005). In publishing its procedures for pediatric euthanasia, the medical center explained that the "approach suits our legal and social culture," although it acknowledged that it was "unclear to what extent it would be transferable to other countries." Eduard Verhagen and Pieter J. J. Sauer, *The Groningen Protocol — Euthanasia in Severely Ill Newborns,* 352 New Eng. J. Med. 959-962 (2005).

The Dutch experience clearly illustrates how rapidly assisted suicide and euthanasia can engulf a nation when the provision of drugs to induce death is viewed as a legitimate medical purpose.

3) *In Belgium, which ignores international standards of medical ethics, legalization of euthanasia has rapidly led to infanticide and disregard for guidelines.*

The Belgian act legalizing euthanasia was passed on May 28, 2002 and went into effect on September 23, 2002.[8] The law limits euthanasia to competent adults and emancipated minors. The Belgian Act on Euthanasia of May 28, 2002, Chap. II, Sec. 3, §1. However, only two years later, lawmakers introduced a proposal to extend euthanasia to children and individuals suffering from dementia. Sénat de Belgique, "Proposition de loi modifiant la loi du 28 mai 2002 relative à l'euthanasie," July 7, 2004, available at http://www.senate.be/wwwcgi/get_pdf?50332915.

According to ruling Flemish Liberal party Senators Jeannine Leduc and Paul Wille who introduced the bill, terminally ill children and teenagers had as much right to

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[8] For text of law, *see The Belgian Act on Euthanasia of May, 28, 2002,* 10 Eur. J. of Health L. 329-335. (2003).

choose when they want to die as anyone else. Allan Hall, *Bill backs euthanasia for children,* The Scotsman, Sept. 9, 2004. The bill did not pass. However, a recent report indicated that physicians in Belgium are, nonetheless, administering lethal drugs to newborns and older infants. Veerle Provoost, *et al, Medical end-of-life decisions in neonates and infants in Flanders,* 365 Lancet 1315 (2005). This has led to new calls to expand the scope of euthanasia.

Embrace of euthanasia by medical professionals has led to the formulation of more convenient ways to euthanize patients. Home "euthanasia kits" will be available soon in more than two hundred Belgian pharmacies so that doctors can carry out in-home deaths with greater ease. The kits, which will contain a barbiturate, a paralyzing agent, an anesthetic, and instructions for use, will cost approximately 45 Euros. Annick Hovine, *La mort à domicile, en kit spécial,* LaLibre, Apr. 15, 2005, available at http://www. lalibre.be/article.phtml?id= 10&subid=90&art_id=215636.

As in the Netherlands, the Belgian experience indicates the danger of disregarding international standards of medical ethics.

IV. Commercial distribution of federally controlled substances that are prescribed under the Oregon Death with Dignity Act is not wholly intrastate in nature.

Providing federally controlled substances for the purpose of assisted suicide under the ODWDA is widely portrayed as solely an intrastate activity. However, the facts regarding the manner in which prescriptions may be filled and where they may be used shatter this image.

Under the ODWDA, the prescribing process for medication that enables patients to end their lives must take place in Oregon. After that, there are no controls on where the prescription may be filled, nor are there any requirements that the patient or the patient's agent personally pick up a filled prescription from a pharmacy.

Controlled substances, like other prescriptions may be filled by mail order.[9] Those prescriptions are convenient, particularly for patients who are severely debilitated or who live in rural areas. Medications are delivered to one's doorstep. This process permits patients to maintain personal privacy. In addition, costs for mail-order prescriptions are less than those filled by local pharmacies. That cost factor has led 22 percent of large employers to require mail-order prescriptions for their employees in 2004. Maria M. Perotin, *Requirements for drugs via mail pits large companies against drugstore chains,* Fort Worth Star-Telegram, Feb. 27, 2005.

The percentage of prescriptions filled by mail-order pharmacies is growing each year. In 1999, mail-order pharmacies accounted for an estimated 10 to 15 percent of the prescription market. Bob Tedeschi, *Want to Be an Online Drugstore? Take a Number,* N.Y. Times, Feb. 2, 1999 and Eric M. Peterson, *Notes & Comments: Doctoring Prescriptions: Federal Barriers to Combating Prescription Drug Fraud against On-Line Pharmacies,* 75 Wash. L. Rev. 1331, 1343 (2000). By 2001, that percentage had reached 17.9 percent. *Mail-Order Prescriptions Again Show Strongest Growth,* 15 Drug Benefit Trends (3) 4 (2003), at http:www.medscape.com/viewarticle/452209 (last accessed Apr. 19, 2005). By the following year it had risen to 18.4 percent. Christopher Rowland, *The Pharmacist is In: Chains Promote Personal Touch to Keep Edge over Mail-order Firms,* Boston Globe, Nov. 10, 2003 at D1. Given the growth trend, it is reasonable to assume that prescriptions for controlled substances, issued under the ODWDA, have been or will be obtained by mail order.

In 1994, during the campaign to legalize assisted suicide in Oregon, the American Association of Retired Persons

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[9] For U.S. Postal Mailing requirements for controlled substances, *see* U.S. Dept. of Justice Drug Enforcement Administration, *Pharmacist's Manual* at 37, available at http://www.deadiversion. usdoj.gov/pubs/manuals/pharm2/phar_content.htm (last accessed April 20, 2005).

(AARP) mail-order pharmacy service confirmed that it could fill a prescription written in Oregon for two hundred 100-mg. capsules of barbiturates, and mail the drugs to the patient either in Oregon or in care of a third party in another state. Diane Gianelli, *Oregon pharmacists wary of assisted-suicide measure,* Am. Med. News, Oct. 24/31, 1994.

When a mail-order pharmacy service is used, drugs prescribed in Oregon pass through interstate channels after the prescription is written.

Currently, AARP pharmacy services will fill any prescription that could be filled at any pharmacy in the United States. The prescription is mailed to AARP's Pennsylvania location, and the prescribed drugs are mailed from there to the patient.[10] In addition, CVS operates a large mail-order pharmacy service.[11] All mail order prescriptions are filled and transported from its Indianapolis location.

Reporting procedures under the Oregon law do not require physicians to know when or where a prescription is filled. Official report forms to be filled out by physicians who write prescriptions request information only up to and including the date on which the lethal dose is prescribed. Oregon Health Services, Center for Health Statistics, *Attending Physician's Compliance Form,* available at http://egov.oregon.gov/DHS/ph/pas/docs/at1form.pdf. The official interview form for follow-up information from prescribing physicians, asking for the date on which the lethal medications were dispensed to the patient, permits "unknown" as a response. Oregon Health Services, Center for Health Statistics, *Oregon Death with Dignity Act*

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[10] Information about AARP's prescription by mail service can be obtained at http://www.aarppharmacy.com/aarpNet/ or by calling 800-289-6031.

[11] Information about the CVS online pharmacy service can be obtained at http://www.cvs.com or by calling 888-607-4287.

Attending Physician Interview Form at 1, available at http://egov.oregon.gov/DHS/ph/pas/docs/mdintdat.pdf.

As indicated above, prescriptions for assisted suicide under the ODWDA can be, and may currently be, filled in other states and transported through other states. Thus, participation in providing federally controlled substances under Oregon's assisted-suicide law currently impacts the federal government's ability to regulate the distribution of federally controlled substances on a national basis. Furthermore, the distribution of federally controlled substances under the ODWDA from outside the state of Oregon violates the laws of other states where filling prescriptions for assisted suicide takes place.

It is unconscionable that a state law would render both the implementing regulations under the Controlled Substances Act and the laws of other states unenforceable. However, if the Ninth Circuit's decision is allowed to stand, that is the effect.

CONCLUSION

The Ashcroft Directive is an appropriate interpretation of a regulation. By barring the use of a federal registration to prescribe federally controlled substances for assisted suicide, the Directive maintains a necessary uniform national standard for dispensing federally controlled drugs. It prevents balkanization in the application of federal regulations related to federally controlled substances, and it does not nullify a law enacted by the state of Oregon. The decision of the Ninth Circuit should be reversed.

Respectfully submitted,

Rita L. Marker
(Counsel of Record)
1233 Maryland Avenue
Steubenville, OH 43952
(740) 282-3810

38

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v.

STATE OF OREGON, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF *AMICUS CURIAE* AMERICANS UNITED FOR LIFE IN SUPPORT OF PETITIONERS

NIKOLAS T. NIKAS
(*Counsel of Record*)
MAILEE R. SMITH
AMERICANS UNITED FOR LIFE
310 South Peoria Street
Suite 300
Chicago, Illinois 60607
312/492-7234

Counsel for Amicus Curiae

May 9, 2005

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
INTEREST OF AMICUS	1
SUMMARY OF ARGUMENT	2
ARGUMENT	3
I. Physician-Assisted Suicide Is Unnecessary For The Treatment Of Pain In Terminally-Ill Patients	5
A. "Uncontrollable pain" can be completely alleviated through palliative care	5
B. Reasons for the existence of uncontrolled pain relate to unwarranted fears, untrained health care professionals, and uninformed patients	10
II. Medical Reasons Are Not Motivating Factors Of Terminally-Ill Patients Seeking Physician-Assisted Suicide	17
CONCLUSION	20

TABLE OF AUTHORITIES

Page

CASES

Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) 1

U.S. v. Moore, 423 U.S. 122 (1975) 3

Vacco v. Quill, 521 U.S. 793 (1997) 1

Washington v. Glucksberg, 521 U.S. 702 (1997) 1, 5, 16

STATUTE AND ATTORNEY GENERAL INTERPRETIVE RULE

Controlled Substances Act, 21 U.S.C. § 801 *et seq.* 3

Office of the Attorney General, Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Nov. 9, 2001) 3

OTHER AUTHORITIES

Carla Alexander, *Palliative and End-of-Life Care*, A GUIDE TO THE CLINICAL CARE OF WOMEN WITH HIV (J. Anderson ed., Heath Resources and Service Admin., HIV/AIDS Bureau, 2001) 8, 9, 11

American Academy of Pain Management et al., Brief of *Amici Curiae* in Support of the Patient Plaintiff-Appellees and in Affirmance of the District Court's Grant of Summary Judgment to Appellees, *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2002) (No. 02-35587) 17

American Geriatrics Society, Brief as *Amicus Curiae* Urging Reversal of the Judgments Below, *Vacco v. Quill*, 521 U.S. 793 (1997) 7, 9, 13

TABLE OF AUTHORITIES – Continued

Page

AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (3rd ed. 1992) 17

American Medical Association et al., Brief of *Amici Curiae* in Support of Petitioners, *Washington v. Glucksberg*, 521 U.S. 702 (1997) 14, 18, 19

American Medical Association, *Module 1: Pain Management: Pathophysiology of Pain and Pain Assessment* (2003), *available at* http://www.ama-cmeonline.com/ 15

American Medical Association, *Module 2: Pain Management: Overview of Management Options* (2003), *available at* http://www.ama-cmeonline.com/ 7, 8, 9, 11

American Medical Association, *Module 3: Pain Management: Barriers to Pain Management and Pain in Special Populations* (2003), *available at* http://www.ama-cmeonline.com/ 10, 12, 14, 15

American Medical Association, *Module 10: Pain Management: Overview and Assessment of Cancer Pain* (2003), *available at* http://www.ama-cmeonline.com/ 8, 14, 15

American Medical Association, *Module 11: Management of Cancer Pain: Pharmacotherapy* (2003), *available at* http://www.ama-cmeonline.com/ 7, 8, 11, 12, 13

American Medical Association, *Module 12: Management of Cancer Pain: Other Analgesic Approaches and End of Life Care* (2003), *available at* http://www.ama-cmeonline.com/ 5, 9

TABLE OF AUTHORITIES – Continued

Page

American Medical Association, *Report 4 of the Council on Scientific Affairs: Aspects of Pain Management in Adults* (1995), *at* http://www.ama-assn.org/ama/pub/category/13672.html ..... *passim*

J. Andrew Billings, *Recent Advances: Palliative Care*, BRITISH MED. J. 2000; 321: 555 7

BLACK'S LAW DICTIONARY (6th ed. 1990) 17

Shannon Brownlee & Joannie M. Schrof, *The Quality of Mercy: Effective Pain Treatments Already Exist. Why Aren't Doctors Using Them?*, U.S. NEWS & WORLD REPORT, Mar. 17, 1997, *available at* http://www.masmith.inspired.net.au/pain/mercy.htm 7, 14

Robert A. Burt, *Constitutionalizing Physician-Assisted Suicide: Will Lightning Strike Thrice?*, 35 DUQ. L. REV. 159 (1996) 6

Ira Byock, *Why Do We Make Dying So Miserable?*, WASHINGTON POST, January 22, 1997, *available at* http://www.afsp.org/about/byock.htm 7, 13

Richard M. Doerflinger, *Conclusion: Shaky Foundations and Slippery Slopes*, 35 DUQ. L. REV. 523 (1996) 10

Federation of State Medical Boards of the United States, Inc., *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004), *at* http://www.ama-assn.org/ama/pub/category/11541.html 12

Kathleen M. Foley, *Improving Palliative Care for Cancer: Summary and Recommendations* (June 19, 2001), *at* http://www4.nationalacademies.org/new.nsf/isbn/s0309075637?OpenDocument 14

TABLE OF AUTHORITIES – Continued

Page

Kathleen M. Foley, *Transforming the Culture of Dying*, PROJECT ON DEATH IN AMERICA: JANUARY 2001-DECEMBER 2003 REPORT OF ACTIVITIES (Open Society Institute, 2004) 6, 16

Phillip D. Good, *Advances in Palliative Care Relevant to the Wider Delivery of Healthcare*, MED. J. OF AUSTRALIA 2003; 179: S44 12

HERBERT HENDIN, SEDUCED BY DEATH: DOCTORS, PATIENTS, AND ASSISTED SUICIDE (1998) ..... *passim*

Herbert Hendin, *Suicide and the Request for Assisted Suicide: Meaning and Motivation*, 35 DUQ. L. REV. 285 (1996) 19

Herbert Hendin, *The Slippery Slope: The Dutch Example*, 35 DUQ. L. REV. 427 (1996) 14

Yale Kamisar, *The "Right to Die": On Drawing (and Erasing) Lines*, 35 DUQ. L. REV. 481 (1996). 11

Gara Lamarche, *What We Have Learned from The Project on Death in America*, PROJECT ON DEATH IN AMERICA: JANUARY 2001-DECEMBER 2003 REPORT OF ACTIVITIES (Open Soc'y Inst., 2004) 16

Timothy Moynihan, *Cancer Pain Treatment: An Interview with a Mayo Clinic Specialist*, October 20, 2003, *at* http://www.mayoclinic.com/invoke.cfm?id=CA00021 ..... 9, 16

NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT (1994) ..... *passim*

NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT (SUPP. TO REPORT) (1997) 11, 12, 13

TABLE OF AUTHORITIES – Continued

Page

Oregon Dep't of Human Serv., *Sixth Annual Report on Oregon's Death with Dignity Act* (2004) 4

Oregon Dep't of Human Serv., *Seventh Annual Report on Oregon's Death with Dignity Act* (2005) 4, 17, 18, 19

Patient-Respondents' Brief in Opposition, *Ashcroft v. Oregon* (No. 04-623) 18

Project on Death in America/Open Society Institute, Brief of *Amicus Curiae* for Reversal of the Judgments Below, *Vacco v. Quill*, 521 U.S. 793 (1997) 6, 15

Timothy Quill & Christine K. Cassel, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, ANNALS OF INTERNAL MED. 2003; 138(3): 208, *available at* http://www.annals.org/cgi/reprint/138/3/208.pdf 6

Timothy E. Quill et al., *The Debate over Physician-Assisted Suicide: Empirical Data and Convergent Views*, ANNALS OF INTERNAL MED. 1998; 128(7): 552, *available at* http://www.annals.org/cgi/content/full/128/7/552 ..... 4, 6

WESLEY J. SMITH, FORCED EXIT: THE SLIPPERY SLOPE FROM ASSISTED SUICIDE TO LEGALIZED MURDER (1997) 7, 9, 10, 12, 16

UNAIDS, AIDS: PALLIATIVE CARE (October 2000) 8

J.C. WILLKE, ASSISTED SUICIDE & EUTHANASIA: PAST & PRESENT (1998) 12

Susan M. Wolf, *Physician-Assisted Suicide in the Context of Managed Care*, 35 DUQ. L. REV. 455 (1996) 18

INTEREST OF AMICUS[1]

Americans United for Life (AUL)[2] is a national, non-profit public interest legal and educational organization founded in 1971. As the oldest pro-life legal organization in the country, AUL is dedicated exclusively to nationwide efforts to reinstate respect for human life in American law and culture.

Over the last 32 years, AUL has filed many amicus briefs with this Court in cases implicating the sanctity of human life and the proper role of the medical profession at the beginning and end of life. Specifically, AUL has filed amicus briefs on behalf of interested parties in this Court's landmark end-of-life decisions: *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990); *Washington v. Glucksberg*, 521 U.S. 702 (1997); and *Vacco v. Quill*, 521 U.S. 793 (1997).

Over the last quarter century, AUL has also provided expert legislative consultation to state legislatures on end-of-life issues involving physician-assisted suicide and withdrawal of nutrition and hydration.

AUL advocates, among other things, that physician-assisted suicide is neither good medical practice nor good public policy. AUL believes that no terminally-ill patient should, or has to, die in pain. AUL also believes that those advocates who push physician-assisted suicide as the only method of pain management for terminally-ill patients are

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[1] This brief is filed with the written consent of the parties. Letters of consent have been filed with the Clerk of this Court.

[2] Alliance Defense Fund, a non-profit public interest organization, located in Scottsdale, Arizona, partially funded the preparation of this brief. No counsel for a party authored this brief in whole or in part.

out of step with the latest advances in palliative care. Since physician-assisted death is never necessary to ensure that terminally-ill patients die peacefully, AUL submits this brief in support of petitioners urging the reversal of the lower court's decision.

SUMMARY OF ARGUMENT

On November 9, 2001, Attorney General John Ashcroft published an interpretive rule under the Controlled Substances Act determining that assisting suicide is not a "legitimate medical purpose." He also recognized that pain management is a legitimate medical purpose. The Attorney General was correct in making this differentiation between physician-assisted suicide (PAS) and pain management.

Importantly, the only medical reason given by advocates of PAS is that assisted suicide is needed to alleviate pain for those patients whose pain is "uncontrollable" or "intolerable." As is evidenced by medical studies and associations, however, PAS is unnecessary for the treatment of pain in terminally-ill patients. Rather, the pain most patients experience can be completely alleviated through medications. The remaining patients can be sedated to a sleep-like state. Thus, pain is not "uncontrollable," but "uncontrolled." Unwarranted fears, untrained health care professionals, and uninformed patients are major barriers to proper pain management in terminally-ill patients.

In addition, there is no evidence that patients in Oregon have sought PAS because their pain is "untreatable" or "uncontrollable." Instead, patients are motivated

primarily by the desire not to lose autonomy or self-worth – neither of which is medical in nature.

For these reasons, the Attorney General was correct in determining that the prescription of controlled substances for PAS is not a legitimate medical purpose. As such, the Attorney General's interpretive rule should be upheld and the lower court's decision should be reversed.

ARGUMENT

The Controlled Substances Act (CSA) establishes a comprehensive, uniform federal scheme to regulate controlled substances in all 50 states. *See* 21 U.S.C. § 801 *et seq*. In *U.S. v. Moore*, this Court implied that the proper standard to utilize in best enforcing the intent of the CSA is a national standard. *See generally U.S. v. Moore*, 423 U.S. 122 (1975).

In accordance with the CSA and the Court's decision in *Moore*, Attorney General John Ashcroft published an interpretive rule on November 9, 2001, which determined, for purposes of the CSA, that assisting suicide is not a "legitimate medical purpose" and that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." Office of the Attorney General, Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607, § 1 (Nov. 9, 2001). On the other hand, the Attorney General acknowledged that pain management has long been recognized as a legitimate medical purpose. *Id*. at § 2. The Attorney General was correct in differentiating between the use of controlled substances for physician-assisted suicide (PAS) and the use of such substances for pain management purposes.

As reported by the Oregon Department of Human Services, the most common reasons patients give for desiring physician-assisted suicide are loss of autonomy, a decreasing ability to participate in activities that make life enjoyable, and loss of dignity. Oregon Dep't of Human Serv., *Seventh Annual Report on Oregon's Death with Dignity Act* 15 (2005); Oregon Dep't of Human Serv., *Sixth Annual Report on Oregon's Death with Dignity Act* 14 (2004).[3] Not one documented case of PAS in Oregon was requested because of untreatable pain.[4] Yet, the examples generally given by proponents of PAS point to the "hard cases" – those cases where PAS is deemed necessary because terminally-ill patients are suffering "uncontrollable" pain. However,

[3] *See also* NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT 25 (1994); HERBERT HENDIN, SEDUCED BY DEATH: DOCTORS, PATIENTS, AND ASSISTED SUICIDE 34 (1998) (HENDIN I); Timothy E. Quill et al., *The Debate over Physician-Assisted Suicide: Empirical Data and Convergent Views*, ANNALS OF INTERNAL MED. 1998; 128(7): 552-558, *available at* http://www.annals.org/cgi/content/full/128/7/552.

[4] While *Amicus* recognizes that, according to Oregon, a small minority of PAS patients has requested suicide on the basis of "inadequate pain control or concern about it," it is important to note that requesting PAS out of a *concern* about *possible* pain is simply not the same as requesting it because a patient is actually *experiencing* pain. *See Seventh Annual Report*, *supra*, at 24; *see also Sixth Annual Report*, *supra*, at 24 (acknowledging that patients discussing concerns about inadequate pain control were not necessarily experiencing pain). Furthermore, there is a significant difference between the "uncontrollable pain" PAS advocates contend requires assisted death and the reality of "inadequate pain control," which, as indicated by the AMA and other sources, results mainly from physicians' lack of pain management awareness and other barriers. *See* Part I.B., *infra*. By creating such an indistinct category as "inadequate pain control or concern about it," the State of Oregon confuses moderate pain, "uncontrollable" pain, and concern about possible pain by placing them all into the same vague grouping. This confusion cannot support the claim that PAS is medically necessary to alleviate pain.

according to studies by the American Medical Association (AMA),[5] the American Pain Society (APS), and the New York State Task Force,[6] such pain is not "uncontrollable," but "uncontrolled."[7] Thus, physician-assisted suicide is simply not necessary to relieve pain and suffering, and any suggestion to the contrary runs counter to medical authorities and studies, as well as to Oregon's annual reports. As such, the Attorney General was correct and reasonable in his determination that the prescription of controlled substances for PAS is not a legitimate medical purpose.

I. PHYSICIAN-ASSISTED SUICIDE IS UNNECESSARY FOR THE TREATMENT OF PAIN IN TERMINALLY-ILL PATIENTS

A. "Uncontrollable pain" can be completely alleviated through palliative care.

Of the reasons given by patients and advocates for the need for PAS, most involve autonomy and self-worth – the

[5] Throughout this brief, *Amicus* cites to various AMA sources, the majority of which are part of the AMA's current continuing medical education program designed specifically to educate physicians on proper pain management, including the end-of-life care of the terminally-ill. *See, e.g.*, AMA, *Module 12: Management of Cancer Pain: Other Analgesic Approaches and End of Life Care* (2003), *available at* http://www.ama-cmeonline.com/.

[6] This Task Force, whose members hold many different views on PAS and euthanasia, was convened by Governor Mario M. Cuomo with the mandate to recommend public policy on issues raised by medical advances. TASK FORCE, *supra*, at vii, xii. This Court cited the Task Force throughout its decision in *Washington v. Glucksberg* and recognized it as "an ongoing, blue-ribbon commission composed of doctors, ethicists, lawyers, religious leaders, and interested laymen." *See Washington v. Glucksberg*, 521 U.S. 702, 719 (1997).

[7] *See* Parts I & II, *infra*.

preservation of neither of which is *medical* in nature.[8] While advocates typically cite to the "hard cases" where terminally-ill patients suffer "uncontrollable" pain during their last days, such cases are "extremely rare" and almost non-existent. TASK FORCE, *supra*, at 40, 93; HENDIN I, *supra*, at 49.

Contrary to claims by other *amici*, most experts in pain management believe that 95 to 98 percent of pain can be relieved in terminally-ill patients.[9] Only two percent of patients in hospice care experience pain that is difficult for a skilled team to manage. Project on Death Brief, *supra*, at Part II.A.1 n.10; Burt, *supra*, at 166 n.37 (citing the AMA). Even proponents of PAS admit that palliative care can relieve most terminal suffering and that the debate focuses on a relatively small number of patients. Quill et al., *supra*, at 208-11.

According to the New York State Task Force, the APS, and the AMA, pain can be effectively treated in most patients simply through the use of analgesic medications

[8] *See* Part II, *infra*, for discussion of the definition of "medical."

[9] Timothy E. Quill & Christine K. Cassel, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, ANNALS OF INTERNAL MED. 2003; 138(3): 208, *available at* http://www.annals.org/cgi/reprint/138/3/208.pdf. *See also* Project on Death in America/Open Society Institute, Brief as *Amicus Curiae* for Reversal of the Judgments Below at Part II.A.1, *Vacco v. Quill*, 521 U.S. 793 (1997) (stating that pain can be alleviated in 98 percent of cases); Robert A. Burt, *Constitutionalizing Physician-Assisted Suicide: Will Lightning Strike Thrice?*, 35 DUQ. L. REV. 159, 166 (1996) (stating that knowledgeable physicians and researchers claim that pain can be alleviated in 98 percent of cases); Kathleen M. Foley, *Transforming the Culture of Dying*, PROJECT ON DEATH IN AMERICA: JANUARY 2001 – DECEMBER 2003 REPORT OF ACTIVITIES 11 (Open Society Institute, 2004) ("Death is inevitable, but severe suffering is not.") (Foley I).

and pain relief techniques. TASK FORCE, *supra*, at 35, 193; AMA, *Report 4 of the Council on Scientific Affairs: Aspects of Pain Management in Adults* ¶ 3 (1995), *at* http://www.ama-assn.org/ama/pub/category/13672.html. *See also* J. Andrew Billings, *Recent Advances: Palliative Care*, BRITISH MED. J. 2000; 321: 555-56. The pain of the remaining patients – who amount to less than three percent – can *always* be relieved through sedation.[10] To put it simply, "[p]ain can always be alleviated," and it is fallacious to claim that killing patients is at times the only method of pain relief. Ira R. Byock, *Why Do We Make Dying So Miserable?*, WASHINGTON POST, January 22, 1997, at ¶ 6, *available at* http://www.afsp.org/about/byock.htm; SMITH, *supra*, at 223.[11]

The basic component of pain management is analgesic medication.[12] TASK FORCE, *supra*, at 37. Two types of medications are widely used: nonsteroidal anti-inflammatory drugs (NSAIDS), such as aspirin and ibuprofen, and opioids, such as codeine and morphine. *Id.* at 37-38.[13] In

[10] American Geriatrics Society, Brief as *Amicus Curiae* Urging Reversal of the Judgments Below at Part I.B, *Vacco v. Quill*, 521 U.S. 793 (1997); WESLEY J. SMITH, FORCED EXIT: THE SLIPPERY SLOPE FROM ASSISTED SUICIDE TO LEGALIZED MURDER 207 (1997).

[11] Moreover, the overwhelming majority of terminally-ill patients do not desire suicide and fight for life until the end. HENDIN I, *supra*, at 34. Even where PAS is requested, in most cases the patient will withdraw the request after proper palliative care has been provided. TASK FORCE, *supra*, at 108 n.113, 120-21.

[12] Obviously, removing the source of the pain is ideal, and the use of chemotherapy and radiation in palliative care is also widely accepted. AMA, *Module 11: Management of Cancer Pain: Pharmacotherapy* 10 (2003), *available at* http://www.ama-cmeonline.com/.

[13] *See also* AMA, *Module 2: Pain Management: Overview of Management Options* 12 (2003), *available at* http://www.ama-cmeonline.com/; Shannon Brownlee & Joannie M. Schrof, *The Quality of Mercy:*

(Continued on following page)

1986, the World Health Organization proposed an "analgesic ladder" approach which has become the guide for the management of all pain. *Id.* at 38.[14] The first step in conquering pain is the use of NSAIDs; the next step is using a weak opioid drug combined with a non-opioid. *Id.*; AMA Module 11, *supra*, at 11. For example, codeine could be combined with acetaminophen. TASK FORCE, *supra*, at 38. Patients with continuing pain could receive a stronger opioid, such as morphine. *Id.*; AMA Module 11, *supra*, at 11.[15] The best relief is provided when analgesic medications are given at regular intervals rather than waiting for pain to intensify.[16] HENDIN I, *supra*, at 235.

Effective Pain Treatments Already Exist. Why Aren't Doctors Using Them?, U.S. NEWS & WORLD REPORT, Mar. 17, 1997, at ¶ 12, *available at* http://www.masmith.inspired.net.au/pain/mercy.htm.

[14] *See also* UNAIDS, AIDS: PALLIATIVE CARE 5 (Oct. 2000); AMA Module 2, *supra*, at 11; AMA Module 11, *supra*, at 11. While most research has concerned cancer and AIDS patients, the AMA instructs that the treatment principles apply to *all types* of persistent pain associated with terminal illnesses. AMA, *Module 10: Pain Management: Overview and Assessment of Cancer Pain* 3 (2003), *available at* http://www.ama-cmeonline.com/.

[15] The combination of an intraspinal administration of opioids and local anesthetic can provide effective pain control when pain is otherwise intractable. TASK FORCE, *supra*, at 40. Anti-depressant medication has also been effective in relieving otherwise intractable pain. HENDIN I, *supra*, at 235; AMA Module 11, *supra*, at 27.

[16] Techniques such as a self-administered opioid drip control pain and help patients maintain their autonomy. TASK FORCE, *supra*, at 135. According to an article published by the U.S. Health Resources & Services Administration, unlike PAS, analgesic medications are also available in liquid and patch forms for those patients who cannot swallow. Carla Alexander, *Palliative and End-of-Life Care*, A GUIDE TO THE CLINICAL CARE OF WOMEN WITH HIV 354 (J. Anderson ed., Heath Resources and Service Admin., HIV/AIDS Bureau, 2001).

The New York State Task Force found that the pain experienced by 90 percent of cancer patients can be alleviated through such pharmacological treatments alone. TASK FORCE, *supra*, at 40. The remaining patients may also gain significant relief from pain through palliative efforts. *Id.* Non-pharmacological therapies can be applied in addition to analgesic and ancillary medications.[17] *Id.* at 39; AMA Report 4, *supra*, at ¶ 12.

For the very small number of patients for whom pharmacological and non-pharmacological remedies do not offer enough relief, sedation to a sleep-like state is available to keep patients from experiencing severe pain and suffering. TASK FORCE, *supra*, at 40; SMITH, *supra*, at 207. Such sedation is now a *widely accepted* medical, ethical, and legal option when patients cannot be helped in any other way, and sedation will *always* eliminate a patient's symptoms near death. American Geriatrics Society Brief, *supra*, at Part III.D.; HENDIN I, *supra*, at 234, 242; AMA Module 12, *supra*, at 14.

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[17] These treatments include cognitive and behavioral approaches such as relaxation exercises and distraction; applications of heat or cold; exercise; anesthetic interventions to block nerve transmission on a temporary or ongoing basis; and neurosurgery to cut nerves. TASK FORCE, *supra*, at 39; AMA Module 2, *supra*, at 9; AMA Module 12, *supra*, at 10-11, 13; AMA Report 4, *supra*, at ¶ 12. Procedures designed to surgically denervate painful areas are available for every level of the nervous system. AMA Module 12, *supra*, at 12. Acupuncture, acupressure, physical therapy, and transcutaneous electrical nerve stimulation (TENS) are also widely used. Alexander, *supra*, at 366; AMA Report 4, *supra*, at ¶ 12; Timothy Moynihan, *Cancer Pain Treatment: An Interview with a Mayo Clinic Specialist* ¶ 7, October 20, 2003, *at* http://www.mayoclinic.com/invoke.cfm?id=CA00021. *See also* AMA Module 2, *supra*, at 9; AMA Module 12, *supra*, at 11, 13.

It is evident that options other than PAS already exist. PAS is simply not necessary to relieve pain and suffering. As such, it is not a "legitimate medical purpose," and the Attorney General's interpretation of the CSA is correct and reasonable. This Court should reverse the Ninth Circuit's decision, and the Attorney General's interpretation should be upheld and enforced.

B. Reasons for the existence of uncontrolled pain relate to unwarranted fears, untrained heath care professionals, and uninformed patients.

Pain exists because it is uncontrolled – not because it is uncontrollable. Dr. Ira Byock, the president of the American Academy of Hospice and Palliative Medicine, states that the only reason that "hard cases" exist at all is because "undertreatment and maltreatment at the end of life is endemic." SMITH, *supra*, at 206. These hard cases result because certain barriers block effective palliative care. *Id.* at 146. Indeed, medical experts agree that a "serious gap" exists between the abilities of modern medicine and the type of palliative care generally received by terminally-ill patients. *Id.* at 147; TASK FORCE, *supra*, at 35; Richard M. Doerflinger, *Conclusion: Shaky Foundations and Slippery Slopes*, 35 DUQ. L. REV. 523, 531 (1996).

There are three primary barriers to the effective treatment of pain: 1) unwarranted fears grounded in palliation myths propagated by advocates of physician-assisted suicide and euthanasia; 2) the lack of training of hospital and health care professionals in pain control methods and palliative care; and 3) the patients' own beliefs and lack of information about pain and pain management. *See* TASK FORCE, *supra*, at xi, 35; AMA, *Module*

3: Pain Management: Barriers to Pain Management and Pain in Special Populations 9 (2003), *available at* http://www.ama-cmeonline.com/.

First, physicians and patients tend to believe the following myths: use of palliative care methods such as analgesics lead to respiratory depression and other side effects; palliative care and analgesics hasten death; and the use of analgesics such as morphine lead to addiction and an unhealthy tolerance of medications which will prohibit pain relief when "really needed." There are also misconceptions about the nature of sedation.

These myths have led physicians to undertreat patients and have led patients to forgo mentioning their pain. However, each myth is baseless. Fears concerning respiratory depression are "unjustifiable" and "unfounded." TASK FORCE, *supra*, at 44; Yale Kamisar, *The "Right to Die": On Drawing (and Erasing) Lines*, 35 DUQ. L. REV. 481, 497 (1996). The AMA reports that patients with severe pain – *i.e.*, the "hard cases" – become *resistant* to the respiratory depressant effects of morphine and morphine-like medications. AMA Report 4, *supra*, at ¶ 30. In addition, patients rapidly develop a tolerance that lessens the impact of respiratory depression and other opioid side effects.[18] TASK FORCE, *supra*, at 162; *see also* NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, WHEN

[18] This tolerance minimizes other side effects, such as mental cloudiness. TASK FORCE, *supra*, at 162. Sedation and cognitive impairment disappear in most patients. AMA Module 2, *supra*, at 26; AMA Module 11, *supra*, at 26. Other side effects such as nausea generally dissipate with continued use, and patients will return to normal or improved functioning. Alexander, *supra*, at 355; AMA Module 2, *supra*, at 26. Most patients are alert and many are capable of independently caring for themselves. *See* Kamisar, *supra*, at 497.

DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT (SUPP. TO REPORT) 17 (1997); SMITH, *supra*, at 222.

Likewise, there is no evidence that pain medications will hasten death if such medications are taken correctly. The New York State Task Force labeled the fear of hastened death one of the "many myths ... which have contributed to the undermedication of patients experiencing treatable pain." TASK FORCE SUPP., *supra*, at 17. Rather, an opioid can be administered safely in large doses when adjusted to control side effects. TASK FORCE, *supra*, at 39. *See also* Phillip D. Good, *Advances in Palliative Care Relevant to the Wider Delivery of Healthcare*, MED. J. OF AUSTRALIA 2003; 179: S44 (stating that recent research indicates that the use of opioids does not influence length of life).

Fears regarding addiction and tolerance are equally unjustifiable, and the AMA instructs that opioids should *never* be withheld from terminally-ill patients for fear of addiction. TASK FORCE, *supra*, at 44; AMA Module 11, *supra*, at 11. Addiction is extremely rare and occurs in only .04 percent of patients treated with morphine. TASK FORCE, *supra*, at 44; J.C. WILLKE, ASSISTED SUICIDE & EUTHANASIA: PAST & PRESENT 102-03 (1998). Physicians and patients must understand that there is a difference between physical dependence, or toleration, and psychological dependence, or addiction.[19] TASK FORCE, *supra*, at 160; Federation of State Medical Boards of the United

[19] Addiction is a "primary, chronic, neurobiologic *disease*" influenced by genetic, psychosocial, and environmental factors, while physical dependence and tolerance merely indicate a state of adaptation. AMA Module 3, *supra*, at 11 (emphasis added).

States, Inc., *Model Policy for the Use of Controlled Substances for the Treatment of Pain* § 7 (2004), *at* http://www.ama-assn.org/ama/pub/category/11541.html. Behaviors that may suggest addiction generally indicate an increase in pain from the progression of the underlying disease. TASK FORCE, *supra*, at 160. Even for patients with a history of addiction, opioids can be used safely and effectively to control pain.[20] AMA Report 4, *supra*, at ¶ 27.

Similarly, physicians and patients must be informed that there is no limit to tolerance of opioids. TASK FORCE SUPP., *supra*, at 162; AMA Module 11, *supra*, at 15. In fact, dosages can be increased without introducing any additional adverse consequences. AMA Report 4, *supra*, at ¶ 32. Therefore, patients need not delay using analgesic medications for fear that such medications will not be effective when "really needed." Larger doses are effective and safe. *Id.*

Finally, physicians and the very few patients who require it need not fear sedation. Most sedated patients die peacefully without suffering, and sedation will *always* work to control pain when a patient is nearing death. American Geriatrics Society Brief, *supra*, at Part III.D.; HENDIN I, *supra*, at 14; Byock, *supra*, at ¶ 6.

The second major barrier to proper pain management is the lack of training of most hospitals and health care

[20] Even if there was a risk of psychological dependence, the New York State Task Force found that the benefits of opioid use would simply outweigh the risks of addiction for patients experiencing significant pain, and especially for patients who are terminally-ill. TASK FORCE, *supra*, at 161.

professionals.[21] Very few physicians realize that it is possible to relieve all pain through proper pain management techniques.[22] HENDIN I, *supra*, at 259. Only a fraction of medical residency programs require a course in pain management, and even fewer teach palliative care.[23] Brownlee & Schrof, *supra*, at ¶ 8. Health care professionals have a limited understanding of the physiology of pain and the pharmacology of analgesics, and clinical care units in the past have had no systems in place to assure that

[21] The AMA asserts that the "ultimate reason" for undertreatment of cancer pain is that physicians and other health care professionals are inadequately educated on pain management. AMA Module 10, *supra*, at 8; *see also* AMA Report 4, *supra*, at ¶ 2 (citing guidelines from the Agency for Health Care Policy & Research as stating that inadequate pain management is widespread and that undertreatment by practitioners is a major cause). The APS agrees, stating that the most common reason for unrelieved pain in U.S. hospitals is the failure of hospital staff to routinely assess pain relief. TASK FORCE, *supra*, at 19.

[22] Interestingly, support for PAS is highest among those health professionals who are the least knowledgeable about pain management – the more physicians know about palliative care, the less likely they are to support legalizing PAS and euthanasia. AMA et al., Brief of *Amici Curiae* in Support of Petitioners at Health Care Background Part D.2, *Washington v. Glucksberg*, 521 U.S. 702 (1997); Herbert Hendin, *The Slippery Slope: The Dutch Example*, 35 DUQ. L. REV. 427, 430-31 (1996).

[23] The AMA reports that in one study, 88 percent of physicians rated their medical school training in cancer pain management as fair or poor, and 73 percent rated their residency training in pain management as fair or poor. AMA Module 3, *supra*, at 9. In 1999, the National Cancer Institute spent less than one percent of its budget on any aspect of research or training in palliative care. Kathleen M. Foley, *Improving Palliative Care for Cancer: Summary and Recommendations* (June 19, 2001), *at* http://www4.nationalacademies.org/new.nsf/isbn/s0309075637?OpenDocument.

pain is recognized and treatments modified. TASK FORCE, *supra*, at 44, 193.[24]

The third major barrier involves the patients' own beliefs and lack of information regarding palliative care. Patients are subject to societal notions, as well as the reactions of their families, which generally disfavor the use of narcotics and other analgesic medications. AMA Report 4, *supra*, at ¶¶ 38-39. Many patients fail to acknowledge pain out of a denial that the disease is progressing. *Id.* at ¶ 34; AMA Module 3, *supra*, at 10. Others prize stoicism and believe that admitting pain is a sign of weakness. TASK FORCE, *supra*, at 46; AMA Module 3, *supra*, at 10; AMA Report 4, *supra*, at ¶ 33. The most reliable indicator of pain is a patient's own report, but pain goes undiagnosed and untreated when patients fail to discuss their pain. AMA, *Module 1: Pain Management: Pathophysiology of Pain and Pain Assessment* 8, 13, 19 (2003), *available at* http://www.ama-cmeonline.com/; AMA Module 10, *supra*, at 15.

On the other hand, patients may have received a negative response in the past after requesting an increased dose of analgesic medication. AMA Report 4, *supra*, at ¶ 35. Many physicians and other health care professionals never address the issue of pain with their

[24] The AMA explains that hospitals and health care professionals also fear potential harassment by state or local regulatory authorities. AMA Report 4, *supra*, at ¶ 16. The agencies most likely to investigate prescribing practices are state medical boards. AMA Module 3, *supra*, at 15. State laws are often more restrictive than federal regulations and even impose limits against medical practices that are fully within medical professional standards. AMA Report 4, *supra*, at ¶ 17. Health care workers also tend to hold misconceptions about regulations and how the restrictions work. Project on Death Brief, *supra*, at Part II.A.1.

patients or fail to do so in a timely, appropriate manner. TASK FORCE, *supra*, at 153; Moynihan, *supra*, at ¶ 8. Such ineffective communication leaves patients uninformed that pain management options and clinics exist. TASK FORCE, *supra*, at 122; SMITH, *supra*, at 206.

When this Court decided *Glucksberg* in 1997, the lack of effective pain relief was a problem that society had only just begun to undertake. *See* TASK FORCE, *supra*, at 137. The New York State Task Force concluded that "[t]he effective implementation of existing clinical knowledge and programs for pain management is almost certain to have an immediate impact on relieving suffering." *Id.* at 159. In 2004, Kathleen Foley, Director of Project on Death in America, stated that the "field of palliative care is definitely much stronger than it was ten years ago." Foley I, *supra*, at 11.

The goal of improving the way in which people die is being reached for more and more people *each day*. Gara Lamarche, *What We Have Learned from The Project on Death in America*, PROJECT ON DEATH IN AMERICA: JANUARY 2001 – DECEMBER 2003 REPORT OF ACTIVITIES 8 (Open Soc'y Inst., 2004). Thus, improvements have been made even since the Attorney General first issued the interpretive rule. As can be seen from the preceding discussion, the proper answer to uncontrolled pain is education and the wider use of effective palliative techniques – not the elimination of the sufferer.

II. MEDICAL REASONS ARE NOT MOTIVATING FACTORS OF TERMINALLY-ILL PATIENTS SEEKING PHYSICIAN-ASSISTED SUICIDE

As quoted by certain *amici* in their Ninth Circuit amicus brief, the ordinary meaning of "medical" is "[p]ertaining to . . . medicine, or the science and art of investigation, prevention, cure, and alleviation of disease." Amer. Acad. of Pain Mgmt. et al., Brief of *Amici Curiae* in Support of the Patient Plaintiff-Appellees and in Affirmance of the District Court's Grant of Summary Judgment to Appellees at 7, *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2002) (No. 02-35587) (quoting BLACK'S LAW DICTIONARY 982 (6th ed. 1990)). The *amici* go on to state that the ordinary meaning of "alleviate" is "[t]o make (pain, for example) more bearable." *Id.* (quoting AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 49 (3rd ed. 1992)). The *amici* erroneously conclude that PAS is legitimate because the ordinary meaning of "medical purpose" includes treatment conducted with the purpose of alleviating disease-related pain. *Id.*

Yet, nowhere in the seven annual reports compiled by the Oregon Department of Human Services[25] is there evidence that any patients sought PAS because their pain was "untreatable" or "uncontrollable." As discussed above,[26] the state of Oregon cannot represent that any patient ever sought PAS because of "untreatable" or "uncontrollable" pain. "Concerns about inadequate

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[25] These annual reports are mandated by the Death with Dignity Act. *See Seventh Annual Report*, *supra*, at 4.

[26] *See supra* n.4 & accompanying text.

pain control" or "inadequate pain control"[27] cannot support a claim that PAS is medically-necessary to alleviate pain. There is simply no evidence that PAS is ever medically required to alleviate pain. Consequently, nothing in Oregon's experience undermines the Attorney General's interpretive rule.[28]

Instead, the most frequently cited concerns across *all seven years* of Oregon's annual reports are the loss of autonomy and the decreased ability to participate in activities that make life enjoyable.[29] *Id.* at 16. Both U.S. and Dutch studies reveal that nonphysical factors and depression are more important than pain and other physical or medical symptoms. Susan M. Wolf, *Physician-Assisted Suicide in the Context of Managed Care*, 35 DUQ. L. REV. 455, 466-68 (1996). Intolerable physical symptoms are simply not the reason most patients request PAS or euthanasia. AMA Brief, *supra*, at Health Care Background Part C.1.

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[27] *See Seventh Annual Report*, *supra*, at 24 (listing "inadequate pain control or concern about it" as a factor in a very small minority of PAS deaths). *But see supra* n.4 & accompanying text.

[28] Contrary to the Patient-Respondents' claim that the Attorney General ignored the data collected by the State of Oregon, the interpretive rule actually reflects the fact that the "medical purpose" of alleviating "uncontrollable" pain does not appear in any of Oregon's annual reports. *See, e.g.*, *Seventh Annual Report*, *supra*, at 24; *see also* Patient-Respondents' Brief in Opposition at 20, *Ashcroft v. Oregon* (No. 04-623). The findings of the New York State Task Force confirm that loss of control and feelings of helplessness may be the most significant factors leading to PAS requests. TASK FORCE, *supra*, at 25.

[29] These concerns were cited by physicians, family members, hospice nurses, and social workers caring for PAS patients in Oregon. *Seventh Annual Report*, *supra*, at 16-17.

What is more common, however, is the *dread* of what *may* happen in the dying process. Herbert Hendin, *Suicide and the Request for Assisted Suicide: Meaning and Motivation*, 35 DUQ. L. REV. 285, 290 (1996); *see also Seventh Annual Report*, *supra*, at 24. The AMA, American Nurses Association, and American Psychiatric Association confirm that the demand for PAS does *not* come primarily from patients *in actual and untreatable pain*, but from those patients who are depressed or fear the possibility of future pain, loss of dignity, or burdening their families. AMA Brief, *supra*, at Part C.

Clearly, these patients are motivated by unjustified fears that could be alleviated with an increased awareness of the effectiveness of palliative care and with the education of their physicians in pain management techniques. The fact that pain itself does not lead patients to request PAS demolishes the argument that PAS is needed to control pain, leaving proponents with no underlying medical need for physician-assisted suicide.

As indicated by the fact that end-of-life pain can be controlled and the fact that pain is not a motivating factor of those patients requesting PAS, the Attorney General's interpretive rule that the prescription of controlled substances for PAS is not a legitimate medical practice is supported by substantial medical evidence and the record in the State of Oregon. As such, the rule should be upheld and enforced.

CONCLUSION

The judgment of the court below should be reversed.

Respectfully submitted,

NIKOLAS T. NIKAS
(*Counsel of Record*)
MAILEE R. SMITH
AMERICANS UNITED FOR LIFE
310 South Peoria Street
Suite 300
Chicago, Illinois 60607
312/492-7234

Counsel for Amicus Curiae

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45

No. 04-623

IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF *AMICUS CURIAE* OF THE THOMAS MORE SOCIETY IN SUPPORT OF PETITIONERS

Paul Benjamin Linton
Counsel of Record
921 Keystone Avenue
Northbrook, Illinois 60062
(847) 291-3848

Thomas Brejcha
Thomas More Society
29 S. La Salle St. Suite 440
Chicago, Illinois 60603
(312) 782-1680

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TABLE OF CONTENTS

Table of Authorities iii

Interest of *Amicus Curiae* 1

INTRODUCTION AND SUMMARY OF ARGUMENT . 2

ARGUMENT:

I. THE COURT OF APPEALS ERRED IN RELYING ON THE "PLAIN STATEMENT" RULE OF *GREGORY V. ASHCROFT*, 501 U.S. 452 (1991), TO ENJOIN THE ATTORNEY GENERAL FROM ENFORCING AN INTERPRETIVE RULE FORBIDDING THE PRESCRIPTION OF CONTROLLED SUBSTANCES FOR THE PURPOSE OF ASSISTING AN INDIVIDUAL IN COMMITTING SUICIDE 8

II. ADOPTION OF THE COURT OF APPEALS' HOLDING WOULD UNDERMINE ENFORCEMENT OF THE CONTROLLED SUBSTANCES ACT AND COMPROMISE THE ATTORNEY GENERAL'S AUTHORITY TO DETERMINE THAT CERTAIN USES OF CONTROLLED SUBSTANCES ARE NOT MEDICALLY LEGITIMATE, ARE NOT CONSISTENT WITH THE PUBLIC INTEREST AND SHOULD BE PROHIBITED, NOTWITHSTANDING CONTRARY STATE LAW. 16

Facilitating Religious Expression 17

Enhancing Athletic Performance 19

Inducing Euphoria 22

Providing Recreation 22

Operating Unauthorized Narcotic Drugs Maintenance Programs 23

Conducting Unregulated Research 24

CONCLUSION 27

TABLE OF AUTHORITIES

Cases:

Amos v. Maryland Dep't of Public Safety and Correctional Services, 126 F.3d 589 (4th Cir. 1998), *vacated and remanded on other grounds*, 524 U.S. 935 (1998) 15

Associated Builders & Contractors v. Perry, 817 F.Supp. 49 (E.D. Mich. 1992) 15

Atascadero State Hospital v. Scanlon, 473 U.S. 234 (1985) 6, 11, 12

Bernal v. Fainter, 467 U.S. 216 (1984) 12

BFP v. Resolution Trust Corp., 511 U.S. 531 (1994) 15

City of Edmonds v. Oxford House, Inc., 514 U.S. 725 (1995) 13

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) 3

Crawford v. Indiana Dep't of Corrections, 115 F.3d 481 (7th Cir. 1997) 15

Cushing v. Moore, 783 F.Supp. 727 (N.D.N.Y. 1992), *aff'd as modified*, 970 F.2d 1103 (2nd Cir. 1992) .. 24

De Sylva v. Ballentine, 351 U.S. 570 (1956) 4

E.E.O.C. v. Commonwealth of Massachusetts, 987 F.2d 64 (1st Cir. 1993) 14

Fry v. D.E.A., 353 F.2d 1041 (9th Cir. 2003) 26

Gately v. Commonwealth of Massachusetts,
2 F.3d 1221 (1st Cir. 1993) 16

Gooding v. United States, 416 U.S. 430 (1974) 9

Gregory v. Ashcroft, 501 U.S. 452 (1991) ..... *passim*

Jerome v. United States, 318 U.S. 101 (1943) 4, 8

Jin Fuey Moy v. United States, 254 U.S. 189 (1920) 24

*League of United Latin American Citizens Council No. 4434
v. Clements*, 986 F.2d 728 (5th Cir. 1993) 16

Leary v. United States, 383 F.2d 851 (5th Cir. 1967),
rev'd on other grounds, 395 U.S. 6 (1969) 18

Luna v. Harris, 888 F.2d 949 (2nd Cir. 1989) 23

McBride v. United States, 225 F.2d 249 (5th Cir. 1955) ... 24

Mississippi Band of Choctaw Indians v. Holyfield,
490 U.S. 30 (1989) ..... *passim*

Native American Church of New York v. United States,
468 F.Supp. 1247 (S.D.N.Y. 1979),
aff'd mem. op., 633 F.2d 205 (2nd Cir. 1980) 18

Nicols v. City of Chicago,
789 F.Supp. 1438 (N.D. Ill. 1992) 15

O Centro Espirita Benficiente Uniao do Vegetal v. Ashcroft,
342 F.3d 1170 (10th Cir. 2003), *on reh'g*,
389 F.3d 973 (10th Cir. 2004) (*en banc*),
cert. granted, April 18, 2005, Docket 04-1084 ... 18

O Centro Espirita Benficiente Uniao do Vegetal v. Ashcroft,
389 F.3d 973 (10th Cir. 2004) (*en banc*),
cert. granted, April 18, 2005,
Docket 04-1084 ..... 18, 19

Olsen v. Drug Enforcement Administration,
878 F.2d 1458 (D.C. Cir. 1989) 18

Oregon v. Ashcroft, 192 F.Supp.2d 1077 (D. Or. 2000) ... 2

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) .. *passim*

Pennsylvania Dep't of Corrections v. Yeskey,
524 U.S. 204 (1998) 15

Peyote Way Church of God, Inc. v. Thornburgh,
922 F.2d 1210 (5th Cir. 1991) 17, 18

Sugarman v. Dougall, 413 U.S. 634 (1973) 6, 12

Taylor v. Beckham, 178 U.S. 548 (1900) 11

Torcasio v. Murray, 57 F.3d 1340 (4th Cir. 1995) 15

United States v. Behrman, 258 U.S. 280 (1922) 24

United States v. Boettjer, 569 F.2d 1078 (9th Cir. 1978),
cert. denied, 435 U.S. 976 (1978) 10

United States v. Castro,
401 F.Supp. 120 (N.D. Ill. 1975) 22

United States v. Collier, 478 F.2d 268 (5th Cir. 1973) 24

United States v. Green, 511 F.2d 1062 (7th Cir. 1975) ... 10

United States v. Henry, 727 F.2d 1373 (5th Cir. 1984),
on reh'g, 749 F.2d 203 (5th Cir. 1984) (*en banc*) .. 22

United States v. Kirk, 584 F.2d 773 (6th Cir. 1978),
cert. denied, 439 U.S. 1048 (1978) 10

United States v. Lot 5, Fox Grove, Alachua County, Florida,
23 F.3d 359 (11th Cir. 1994),
cert. denied, 513 U.S. 1076 (1995) 6, 14

United States v. Moore, 423 U.S. 122 (1975) 10, 24

United States v. Norris, 780 F.2d 1207 (5th Cir. 1986) ... 10

United States v. Oakland Cannabis Buyers' Cooperative,
532 U.S. 483 (2001) 10, 26

United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975),
cert. denied, 423 U.S. 1031 (1975) 9

United States v. Vamos, 797 F.2d 1146 (2nd Cir. 1986),
cert. denied, 479 U.S. 1036 (1987) 10

United States v. Whitley, 734 F.2d 1129 (6th Cir. 1984) .. 22

Webb v. United States, 249 U.S. 960 (1919) 24

Whyte v. United States, 471 A.2d 1018
(D.C. Ct. App. 1984) 18

Yeskey v. Commonwealth of Pennsylvania
Dep't of Corrections, 118 F.3d 168 (3rd Cir. 1997),
aff'd, 524 U.S. 204 (1998) 15

Statutes and Regulations:

21 U.S.C. § 801 *et seq.* (2000) 2

21 U.S.C. § 802(41)(A) (2000) 19

21 U.S.C. § 812(c), Schedule I (c)(11) (2004) 17

21 U.S.C. § 812(c), Schedule I (c)(12) (2000) 17

21 U.S.C.§ 812(c), Schedule II(a)(4) (2000) 22

21 U.S.C. § 812(c), Schedule III(e) (2000) 19

21 U.S.C. § 823 (2000) 5, 9, 25

21 U.S.C. § 823(f) (2000) ..... *passim*

21 U.S.C. § 823(f)(5) (2000) 25

21 U.S.C. § 823(g) (Supp. 2005) 23

21 U.S.C. § 823(g)(2)(B) (Supp. 2005) 23

21 U.S.C. § 823(g)(2)(C) (Supp. 2005) 23

21 U.S.C. § 823(g)(2)(D) (Supp. 2005) 23

21 U.S.C. § 823(g)(2)(E)(i) (Supp. 2005) 23

21 U.S.C. § 824(a) (2000) 25

21 U.S.C. § 824(a)(4) (2000) 2, 23, 25

21 U.S.C. § 877 (2000) 3

29 U.S.C. § 621 *et seq.* (2000) 5, 11

29 U.S.C. § 623(1) (2000) 11

29 U.S.C. § 630(f) (2000) 6, 12

29 U.S.C. § 631(a) (2000) 11

42 U.S.C. § 1996a (2000) 17

42 U.S.C. § 2000bb *et seq.* (2000) 18

118 Stat. 1661 21

84 Stat. 1236, § 100 *et seq.* 13

38 Stat. 785 ..... 6, 13

34 Stat. 768 13

21 C.F.R. § 166.3(c) 17

21 C.F.R. § 1301.18 (2004) 25

21 C.F.R. § 1301.22 (2004) 25

21 C.F.R. § 1304.03(c) (2004) 23

21 C.F.R. § 1304.03(d) (2004) 23

21 C.F.R. § 1304.04(f) (2004) 23

21 C.F.R. § 1304.22(c) (2004) 25

21 C.F.R. § 1304.24 (2004) 23

21 C.F.R. § 1304.25 (2004) 23

21 C.F.R. § 1306.04(a) (2004) 2

21 C.F.R. § 1306.07(a) (2004) 23

21 C.F.R. § 1307.31 (2004) 17

21 C.F.R. § 1308.11(d)(21) (2004) 17

21 C.F.R. § 1308.11(d)(23) (2004) 17

21 C.F.R. § 1308.12(b)(4) (2004) 22

21 C.F.R. § 1308.13(f) (2004) 19

66 Fed. Reg. 56,608 2

Mo. Const. art. V, § 26 (West 1995) 11

OR. REV. STAT. § 127.800 *et seq.* (2003) 2

Other Authorities:

H.R. 91-1444, 91st Cong., 2nd Sess. (1970),
reprinted in 1970 U.S.C.C.A.N. 4566 13

S.. Rep. No. 98-225 at 267, 98th Cong., 2nd Sess. (1984),
reprinted in 1984 U.S.C.C.A.N. 3182 25

House Committee on Government Reform,
Hearings on Steroid Use in Sports, March 17, 2005
http://reform.house.gov/GovReform/Hearings/
Event Single.aspx?EventID1637 19-21

Joseph F. Spillane, "The Road to the Harrison Narcotics
Act: Drugs and Their Control, 1875-1918,"
FEDERAL DRUG CONTROL[:]
THE EVOLUTION OF POLICY AND PRACTICE
(Haworth Press 2004) (Jonathon Erlen & Joseph F.
Spillane, Eds.) 13

Interest of *Amicus Curiae*[*]

The Thomas More Society is a non-sectarian 501(c)(3) public charity based in Chicago, Illinois, and is incorporated as an Illinois not-for-profit corporation. Founded in 1997, the Thomas More Society was established to help meet the burgeoning legal needs of the pro-life movement and, in particular, to defend those who face legal battles as a result of their commitment to the protection of basic civil rights for the most vulnerable and defenseless members of our society, innocent prenatal human beings. The Thomas More Society provides legal advice and assistance to those who face harassment, employment discrimination, unjust treatment or prosecution as a result of their pro-life position.

The Thomas More Society approves of appropriate public policies to protect innocent human life at all stages of life, from conception to natural death. Consistent with its mission and the respect for human life which that mission implies, the Thomas More Society opposes state-sanctioned physician-assisted suicide and supports the Attorney General's rule prohibiting the prescription of controlled substances to facilitate physician-assisted suicide. A ruling by this Court affirming the Ninth Circuit would undermine enforcement of the Controlled Substances Act and compromise the authority of the Attorney General to determine that certain uses of controlled substances, including the prescription of such substances for the purpose of assisting an individual in committing suicide, are not medically legitimate, are not consistent with the public interest and should be prohibited, notwithstanding contrary state law. To assist the Court in addressing the issues presented, *amicus* submits this brief.

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[*] Letters of consent have been filed with the Clerk. None of the counsel for the parties authored this brief in whole or in part, and no one other than *amicus* or its counsel has contributed money or services to the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

For more than thirty years, Department of Justice regulations implementing the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.* (2000), have provided that a prescription for drugs covered by the Act is valid only if issued for a "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (2004). On November 6, 2001, the Attorney General issued an interpretive ruling, effective November 9, 2001, to clarify that a prescription of a controlled substance issued for the purpose of assisting an individual in committing suicide is not one made for a "legitimate medical purpose" within the meaning of § 1306.04(a), and that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." 66 Fed. Reg. 56,608. "Such conduct by a physician registered to dispense controlled substances," the Attorney General warned, "may 'render his registration * * * inconsistent with the public interest' and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4)." *Id.*, quoting 21 U.S.C. § 824(a)(4). The Attorney General specifically noted that this conclusion applies "regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted." *Id.*

Respondents, the State of Oregon, which allows physician assisted suicide, OR. REV. STAT. § 127.800 *et seq.* (2003), and others, challenged the interpretive rule in the United States District Court for the District of Oregon. The district court held the rule invalid and enjoined petitioners "from enforcing, applying, or otherwise giving any legal effect" to the rule. *Oregon v. Ashcroft*, 192 F.Supp.2d 1077, 1080 (D. Or. 2000). On appeal, the court of appeals held that

the district court had lacked jurisdiction over respondents' action and treated the case as a petition for review under 21 U.S.C. § 877 that had been mistakenly filed in the district court and transferred to the court of appeals. *Oregon v. Ashcroft*, 368 F.3d 1118, 1120-21 (9th Cir. 2004). On the merits, a divided court granted the petitions for review and "continued" the district court's injunction. *Id.* at 1131.

The majority held that the Attorney General lacked statutory authority to issue the rule in question. The interpretive rule "violates the 'clear statement' rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress." 368 F.3d at 1123. With respect to the first reason, which is the subject of this brief, the court noted that the States, not the federal government, are "'the primary regulators of professional [medical] conduct.'" *Id.* at 1124, quoting *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002). Accordingly, "state governments bear the primary responsibility for evaluating physician assisted suicide . . . ." *Id.* The Attorney General's interpretive rule, however, "interferes with Oregon's authority to regulate medical care within its borders" by "criminalizing medical practices specifically authorized under Oregon law [*i.e.*, the use of physician prescribed controlled substances to assist a terminally ill patient in committing suicide]." *Id.* This "interference," according to the majority, "'alter[s] the usual constitutional balance between the States and the Federal Government.'" *Id.*, quoting *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (internal quotation marks and citation omitted). "Under these circumstances," the court determined, "'it is incumbent upon the federal courts to be certain of Congress' intent' before finding that federal authority supercedes state law." *Id.* at 1124-25, quoting *Gregory*, 501 U.S. at 460 (internal quotation marks and citation omitted).

The majority held that in the absence of an "'unmistakably clear'" authorization from Congress, "the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care." *Id.* at 1125, quoting *Gregory*, 501 U.S. at 460 (internal quotation marks and citation omitted). The court found "no indication–much less an 'unmistakably clear' indication–that [Congress] intended to authorize the Attorney General to regulate the practice of physician assisted suicide." *Id.* "By attempting to regulate the practice of physician assisted suicide, the [interpretive rule] invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice." *Id.* The majority concluded that the interpretive rule "violates the clear statement rule" because "Congress has not clearly authorized such an intrusion [into the State's authority to regulate medical practice]." *Id.*

Senior Judge Wallace dissented. The majority's reliance on the "clear statement" rule was misplaced and ignored controlling Supreme Court precedents, as well as the text of the Controlled Substances Act itself. 368 F.3d at 1136-37. Although "federal law occasionally incorporates state-law definitions by reference, *id.*, at 1136, citing *De Sylva v. Ballentine*, 351 U.S. 570, 580-82 (1956) (defining the word "children" in a federal statute according to state law), "recourse to state law is the exception rather than the norm." *Id.* "[T]he general assumption [is] that 'in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute [does] not mak[e] the application of the federal act dependent on state law.'" *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989), quoting *Jerome v. United States*, 318 U.S. 101, 104 (1943).

The dissent noted that there is no language in the Controlled Substances Act suggesting that Congress intended

the Act to be dependent upon state law. "State law may be *relevant* to certain provisions of the . . . Act," 368 F.3d at 1137, citing 21 U.S.C. § 823 (f) (instructing the Attorney General to consider state-law violations when deciding whether a physician's registration would be contrary to the public interest), "but nothing in the Controlled Substances Act plainly evinces a congressional intent to define 'the public interest' solely according to state law." *Id.* Section 823 "instructs the Attorney General to identify acts 'inconsistent with the public interest' by reference to a variety of sources, including a physician's federal conviction record, compliance with 'Federal . . . laws relating to controlled substances,' and 'other conduct which may threaten public health and safety.'" *Id.*, quoting 21 U.S.C. § 823. Thus, "[t]he majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band's* 'plain indication' rule and contravenes Congress' clearly expressed intent." *Id.* *Amicus curiae* concurs with Senior Judge Wallace's dissent.

1. The majority's reliance on *Gregory v. Ashcroft*, 501 U.S. 452 (1991), was clearly misplaced. At issue in *Gregory* was whether the Age Discrimination in Employment Act (ADEA), 29 U.S.C. § 621 *et seq.* (2000), applied to state court judges who had been appointed to office by the Governor of Missouri and who were required to retire by age 70 by a provision of the Missouri Constitution. The Court noted that the mandatory retirement provision "goes beyond an area traditionally regulated by the States; it is a decision of the most fundamental sort for a sovereign entity. Through the structure of the government, and the character of those who exercise government authority, the State defines itself as a sovereign." 501 U.S. at 460. If Congress intends to alter the "'usual constitutional balance between the States and the Federal Government,'" it must make its intention to do so

"'unmistakably clear in the language of the statute.'" *Id.*, quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985). The "plain statement" rule applies to "state decisions that 'go to the heart of representative government.'" *Id.* at 461, quoting *Sugarman v. Dougall*, 413 U.S. 634, 647 (1973). In *Gregory*, the Court determined that the ADEA was at least ambiguous whether a state judge is an "appointee on the policymaking level," within the meaning of 29 U.S.C. § 630(f), and therefore excluded from the scope of the Act. *Id.* at 467. In the absence of a "plain indication" that Congress intended to include appointed judges within the scope of the Act, the Court declined to attribute such an intent to Congress. *Id.* at 470.

The court of appeals gave *Gregory* an overly broad reading. The "plain statement" rule, properly understood, "is limited to federal laws impacting a [S]tate's self-identification as a sovereignty," not to a State's "substantive policy choice[s]." *United States v. Lot 5, Fox Grove, Alachua County, Florida*, 23 F.3d 359, 362 (11th Cir. 1994), *cert. denied*, 513 U.S. 1076 (1995). Oregon's decision to legalize physician-assisted suicide, however, is simply a "substantive policy choice" on behalf of the State, not part of the State's "self-identification as a sovereignty." The "regulation of medical care" may be an area "traditionally reserved for state authority," 368 F.3d at 1125, but that is not enough to invoke the "plain statement" rule. In *Gregory*, the Court stressed that the mandatory retirement provision in the Missouri Constitution "*goes beyond an area traditionally regulated by the States*, ..." 501 U.S. at 460 (emphasis added). Moreover, although the regulation of the practice of medicine may be a matter "traditionally reserved for state authority," the same cannot be said of the regulation of controlled substances which, since adoption of the Harrison Narcotics Act of 1914, 38 Stat. 785, has been a matter of profound *federal* interest.

2. The majority's application of the "plain statement" rule to the Controlled Substances Act dramatically undermines the Attorney General's authority to enforce the Act and federal drug control policy. According to the majority, absent an "unmistakably clear" indication from Congress that it intended to authorize the Attorney General to regulate the specific purposes for which controlled substances may be prescribed (*e.g.*, physician-assisted suicide), each State may decide for itself the purposes for which such substances may be prescribed. Thus, under the majority's holding, a State could authorize controlled substances to be used for a variety of purposes–facilitating religious expression, enhancing athletic performance, inducing euphoria, providing recreation, operating unauthorized narcotic drugs maintenance programs and conducting unregulated research (with Schedule I substances), as well as assisting suicide–and the Attorney General would be powerless to do anything about it. The State's authorization of controlled substances for those purposes would effectively preclude the Attorney General from taking any action–civil, administrative or criminal–against a registrant acting in compliance with state law. A holding that leads to such extraordinary results cannot be reasonable.

Adoption of the majority's reasoning would inevitably result in the Balkanization of medical practice, in which each State would be free to decide for itself whether a controlled substance could be used for a given purpose, no mater how unethical, unorthodox, untested or unusual. Under the majority's holding, conduct that otherwise could result in suspension or revocation of a physician's registration to dispense federal controlled substances, or even criminal prosecution, would be immune from federal control by virtue of state law authorizing the specific purposes for which controlled substances may be prescribed. That is clearly not what Congress intended in enacting the Controlled Substances Act.

ARGUMENT

I. THE COURT OF APPEALS ERRED IN RELYING ON THE "PLAIN STATEMENT" RULE OF *GREGORY V. ASHCROFT*, 501 U.S. 452 (1991), TO ENJOIN THE ATTORNEY GENERAL FROM ENFORCING AN INTERPRETIVE RULE FORBIDDING THE PRESCRIPTION OF CONTROLLED SUBSTANCES FOR THE PURPOSE OF ASSISTING AN INDIVIDUAL IN COMMITTING SUICIDE.

The court of appeals held that the Attorney General was powerless to proscribe the prescription of controlled substances for the purpose of assisting an individual in committing suicide in the absence of an "unmistakably clear" expression of Congressional intent authorizing him to so interpret the Controlled Substances Act. 368 F.3d at 1125. In so ruling, the majority relied principally on this Court's decision in *Gregory v. Ashcroft*, 501 U.S. 452 (1991). *Id.* at 1124-25. That reliance was clearly misplaced.

1. Under well-established precedent, "the general assumption [is] that 'in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law.'" *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989), quoting *Jerome v. United States*, 318 U.S. 101, 104 (1943). "One reason for this rule of construction is that federal statutes are generally intended to have uniform nationwide application." *Id.*, citing *Jerome*. "A second reason for the presumption against the application of state law is the danger that 'the federal program would be impaired if state law were to control.'" *Id.* at 44, quoting *Jerome*, 318 U.S. at 104. Both reasons apply here.

First, as Senior Judge Wallace noted in his dissent, 368 F.3d at 1137, there is no language in the Controlled Substances Act suggesting that Congress intended the Act to be dependent upon state law. Although "State law may be *relevant* to certain provisions of the . . . Act," *e.g.*, 21 U.S.C. § 823(f) (instructing the Attorney General to consider state law violations when deciding whether a physician's registration would be contrary to the public interest), "nothing in the Controlled Substances Act plainly evinces a congressional intent to define 'the public interest' solely according to state law." *Id.* Section 823 "instructs the Attorney General to identify acts 'inconsistent with the public interest' by reference to a variety of sources, including a physician's federal conviction record, compliance with 'Federal . . . laws relating to controlled substances,' and 'other conduct which may threaten public health and safety.'" *Id.*, quoting 21 U.S.C. § 823. Thus, "[t]he majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band's* 'plain indication' rule and contravenes Congress' clearly expressed intent." *Id.*[1]

This Court has recognized that in enacting the Controlled Substances Act, Congress intended to provide "a comprehensive *federal* scheme for the control of drug abuse." *Gooding v. United States*, 416 U.S. 430, 449 (1974) (emphasis added). To be effective, enforceable and uniform, such a scheme must rely on a general standard of medical

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[1] The majority also ignored its own precedent. *See United States v. Rosenberg*, 515 F.2d 190, 198 n.14 (9th Cir. 1975) (rejecting the argument that a federal prosecution under the Controlled Substances Act could not proceed unless and until there had been a finding that the defendant's conduct was unauthorized under state law), *cert. denied*, 423 U.S. 1031 (1975).

care that exists throughout the United States, not one that turns on the peculiarities of each State's law. *See United States v. Moore*, 423 U.S. 122, 139 (1975) (approving jury instruction that, under the Controlled Substances Act, prescriptions must be made "in accordance with a standard of medical practice generally recognized and accepted in the United States").[2]

Second, for the reasons developed in more detail in the following argument, it is evident that the purposes of the Controlled Substances Act would be seriously undermined if, as the majority held, state law were to control what constitutes the permissible uses of substances subject to the Act. Suffice it to say here that the very concept of a *federal* controlled substances act would be compromised if *state* law ultimately determined the permissible uses of controlled substances. *See United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (rejecting claim that Californians who used marijuana for medical purposes "upon the recommendation or approval of a physician" in compliance with California law were exempt from the prohibitions of the Controlled Substances Act which classifies marijuana as a Schedule I substance with no recognized medical use).

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[2] *See also United States v. Norris*, 780 F.2d 1207, 1209 & n. 2 (5th Cir. 1986) ("a standard medical practice may [not] be based on an entirely subjective standard" but must be one "recognized and accepted in the United States"); *United States v. Vamos*, 797 F.2d 1146, 1153 (2nd Cir. 1986) ("[t]o permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken our drug laws in a critical area"), *cert. denied*, 479 U.S. 1036 (1987); *United States v. Kirk*, 584 F.2d 773, 785 (6th Cir. 1978) (relying on "generally acceptable standards of medical practice for issuing prescriptions"), *cert. denied*, 439 U.S. 1048 (1978); *United States v. Boettjer*, 569 F.2d 1078, 1081 (9th Cir. 1978) (same), *cert. denied*, 435 U.S. 976 (1978); *United States v. Green*, 511 F.2d 1062, 1073 (7th Cir. 1975) (same)

2. The majority erred in relying on *Gregory v. Ashcroft* to circumvent the "plain indication" rule of *Mississippi Band*. The issue in *Gregory* was whether the ADEA, 29 U.S.C. § 621 *et seq.*, which makes it unlawful for an "employer" "to discharge any individual" who is at least 40 years old "because of such individual's age," 29 U.S.C. §§ 523(1), 631(a), applies to state court judges who had been appointed to office by the Governor of Missouri and who were subject to mandatory retirement at age 70 by art. V, § 26, of the Missouri Constitution. MO. CONST. art. V, § 26 (West 1995).

The Court began its analysis of the issue by noting that art. V, § 26, "goes beyond an area traditionally regulated by the States; it is a decision of the most fundamental sort for a sovereign entity. Through the structure of its government, and the character of those who exercise government authority, a State defines itself as a sovereign." 501 U.S. at 460. The States' power to "'prescribe the qualifications of their own officers'" is "'essential to [their] independence'" and "'should be exclusive and free from external interference, except so far as plainly provided by the Constitution of the United States.'" *Id.*, quoting *Taylor v. Beckham*, 178 U.S. 548, 570-71 (1900).

The Court observed that "Congressional interference with [the] decision of the people of Missouri, defining their constitutional offices, would upset the usual constitutional balance of federal and state powers." 501 U.S. at 460. For that reason, "'it is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides' this balance." *Id.*, quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 243 (1985). Where Congress intends to alter the "'usual constitutional balance between the States and the Federal Government,'" it must makes its intention to do so "'unmistakably clear in the language of the

statute." *Id.*, quoting *Atascadero*. "This plain statement rule," the Court explained, "is nothing more than an acknowledgment that the States retain substantial powers under our constitutional scheme, powers with which Congress does not readily interfere." *Id.* at 461.

The Court referred to a recent line of authority in which it has "acknowledged the unique nature of state decisions that 'go to the heart of representative government.'" *Gregory*, 501 U.S. at 461, quoting *Sugarman v. Dougall*, 412 U.S. 634, 647 (1973). Under this line of authority, the Court has considered the authority of state and local governments to prohibit aliens from public employment and has applied a lower standard of review than strict scrutiny "when evaluating the validity of exclusions [from public employment] that entrust only to citizens important elective and nonelective positions whose operations 'go to the heart of representative government.'" *Bernal v. Fainter*, 467 U.S. 216, 221 (1984), quoting *Sugarman*, *supra*. The "political function" cases recognize "the authority of the people of the States to determine the qualifications of their most important government officials." *Gregory*, 501 U.S. at 463.

Turning to the question at hand, the Court noted that the ADEA excludes from the definition of employee "an appointee on the policymaking level" chosen by "any person elected to public office in any State . . . ." *Gregory*, 501 U.S. at 465, quoting 29 U.S.C. § 630(f). After reviewing the authority of Missouri state court judges, including their power to interpret and develop the common law, the Court found that it was "at least ambiguous whether a state judge is an 'appointee on the policymaking level,'" and thus excluded from the coverage of the Act. *Id.* at 467. Because Congress did not make it clear that judges are included, the Court concluded that the Act does not cover them. *Id.* at 470.

3. *Gregory* has no application to the Controlled Substances Act. First, in *Gregory*, the Court stressed that the state constitutional provision at issue "*goes beyond an area traditionally regulated by the States*, ..." 501 U.S. at 460 (emphasis added). *See City of Edmonds v. Oxford House*, Inc., 514 U.S. 725, 732 n. 5 (1995) (emphasizing this aspect of *Gregory*). Thus, the majority's observation that the "regulation of medical care" is "an area of law traditionally reserved for state authority," 368 F.3d at 1125, does not, in and of itself, implicate the "plain statement" rule. Second, although regulation of the practice of medicine may be a matter "traditionally reserved for state authority," the same certainly cannot be said of the regulation of controlled substances. For more than 90 years, from adoption of the Harrison Narcotics Act of 1914, 38 Stat. 785, through enactment of the Controlled Substances Act of 1970, 84 Stat. 1236, § 100 *et seq.*, the regulation of controlled substances has been a matter of continuing and uninterrupted *federal* interest.[3]

Gregory's "plain statement" rule does not apply unless "provisions [of federal law] are ambiguous *and* state

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[3] Indeed, one commentator has pointed out that "[a]lthough the Harrison Narcotics Act was certainly an important milestone in the history of drug control, it hardly represented the first use of the criminal law in this area, even at the federal level [citing the Pure Food and Drug Act of 1906, 34 Stat. 768, and various national and international efforts to ban opium smoking and importation of opium for smoking before 1914]." Joseph F. Spillane, "The Road to the Harrison Narcotics Act: Drugs and Their Control, 1875-1918," FEDERAL DRUG CONTROL[:] THE EVOLUTION OF POLICY AND PRACTICE at 10 (Haworth Press 2004) (Jonathon Erlen & Joseph F. Spillane, Eds.). *See also* H.R. 91-1444, 91st Cong., 2nd Sess. (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571 (noting that since 1914, "the Congress has enacted more than 50 pieces of legislation relating to control and diversion, from legitimate channels, of those drugs referred to as narcotics and dangerous drugs").

sovereignty is at issue, ..." *E.E.O.C. v. Commonwealth of Massachusetts*, 987 F.2d 64, 69 (1st Cir. 1993) (*Gregory* did not prevent the E.E.O.C. from using the ADEA to overturn a Massachusetts law that required state and local officials and general employees who are seventy years old or older to take and pass a medical examination as a condition of continued employment). For the reasons set forth above, the provisions of the Controlled Substances Act are not ambiguous and state sovereignty is not at issue in the regulation of the use of federally controlled substances.

The Eleventh Circuit has held that "the *Gregory* plain statement rule is limited to federal laws impacting a [S]tate's self-identification as a sovereignty." *United States v. Lot 5, Fox Grove, Alachua County, Florida*, 23 F.3d 359, 362 (11th Cir. 1994) (federal civil forfeiture law preempts Florida's constitutional homestead right). In *United States v. Lot 5*, the court of appeals noted that Florida's homestead protection is "a substantive policy choice, not a means of sovereign definition." *Id.* So, too, Oregon's decision to decriminalize the use of controlled substances for physician assisted suicide simply represents a "substantive policy choice" of the State and is not a means of "sovereign definition."[4]

This Court has intimated (and lower courts have held) that "exercising ultimate control over the management of

[4] Nothing in the Attorney General's interpretive rule affects the legality of assisted suicide under Oregon law, other than the use of controlled substances to facilitate suicides. Other means of assisting suicide, *e.g.*, inhalation of gasses or ingestion of substances not covered by the Controlled Substances Act, would remain available options, as the dissent noted. 368 F.3d at 1134-35 (Wallace, Senior Judge, dissenting). The rule does not prevent "[s]tate legislators [from] authoriz[ing] alternative methods for assisting suicide that do not involve the prescription of controlled substances." *Id.* at 1148.

state prisons, like establishing the qualifications of state government officials, is a traditional and essential function subject to the plain statement rule of *Gregory*." *Pennsylvania Dep't of Corrections v. Yeskey*, 524 U.S. 204, 209 (1998).[5] The Court has also relied, in part, on *Gregory* in holding that States have an "essential sovereign interest in the security and stability of title to land." *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 544 n. 8 (1994). A state law decriminalizing assisted suicide, however, affects only private conduct and does not trench upon the "sovereign interest[s]" of the State.

Gregory's "plain statement" rule has been held *not* to apply to federal labor regulation of "the relationship between a local government employer and its employees," *Nicols v. City of Chicago*, 789 F.Supp. 1438, 1446 (N.D. Ill. 1992), or to ERISA's impact on state labor statutes, even though such matters "traditionally [have been] regulated at the state level." *Associated Builders & Contractors v. Perry*, 817 F.Supp. 49, 53-54 n.3 (E.D. Mich. 1992). In the latter case, the district court noted that state laws regulating labor relations "certainly do not rise to the level of 'the most fundamental sort for a sovereign entity.'" *Id.*, quoting *Gregory*, 501 U.S. at 460. The plain statement rule has also been held not to apply to a provision of the Voting Rights Act that "impinges on the authority of [S]tates to employ certain election practices," but not on their authority "to set

[5] *See Torcasio v. Murray*, 57 F.3d 1340, 1345 (4th Cir. 1995) ("the management of state prisons is a core state function"); *Amos v. Maryland Dep't of Public Safety and Correctional Services*, 126 F.3d 589, 600 (4th Cir. 1998) (adhering to *Torcasio*), *vacated and remanded on other grounds*, 524 U.S. 935 (1998); *Crawford v. Indiana Dep't of Corrections*, 115 F.3d 481, 485-86 (7th Cir. 1997) (same); *Yeskey v. Commonwealth of Pennsylvania Dep't of Corrections*, 118 F.3d 168, 173 (3rd Cir. 1997) (same), *aff'd*, 524 U.S. 204 (1998).

qualifications for their elected officials." *League of United Latin American Citizens Council No. 4434 v. Clements*, 986 F.2d 728, 759 (5th Cir. 1993). *See also Gately v. Commonwealth of Massachusetts*, 2 F.3d 1221 (1st Cir. 1993) (declining to apply *Gregory's* "plain statement" rule to the ADEA's invalidation of state policy mandating retirement of state police). Oregon's interest in allowing controlled substances to be used in facilitating physician-assisted suicide is no greater than any of the state interests asserted, but found wanting, in the foregoing cases.

The court of appeals erred in relying on the "plain statement" rule of *Gregory v. Ashcroft* to enjoin the Attorney General from enforcing his interpretive rule barring the use of controlled substances for the purpose of assisting an individual in committing suicide. Because that error was central to the court's analysis, its judgment should be reversed.

II. ADOPTION OF THE COURT OF APPEALS' HOLDING WOULD UNDERMINE ENFORCEMENT OF THE CONTROLLED SUBSTANCES ACT AND COMPROMISE THE ATTORNEY GENERAL'S AUTHORITY TO DETERMINE THAT CERTAIN USES OF CONTROLLED SUBSTANCES ARE NOT MEDICALLY LEGITIMATE, ARE NOT CONSISTENT WITH THE PUBLIC INTEREST AND SHOULD BE PROHIBITED, NOTWITHSTANDING CONTRARY STATE LAW.

The holding of the court of appeals, if adopted by this Court, would undermine enforcement of the Controlled Substances Act and compromise the Attorney General's authority to determine that certain uses of controlled substances, including the prescription of such substances for the purpose of assisting an individual in committing suicide,

are not medically legitimate, are not consistent with the public interest and should be prohibited, notwithstanding contrary state law. Under the court of appeals' holding, the Attorney General may not prohibit the prescription, dispensing or administration of controlled substances for any purposes allowed by state law, in the absence of an "unmistakably clear" indication from Congress authorizing him to do so. 368 F.3d at 1125.[6] The possible consequences of such a holding, if not reversed by this Court, are not difficult to foresee.

Facilitating Religious Expression

For forty years, first by regulation, 21 C.F.R. § 166.3(c), recodified as 21 C.F.R. § 1307.31 (2004), later by statute, 42 U.S.C. § 1996a (2000), federal law has allowed the traditional religious use of peyote by members of Indian tribes. The stems of peyote, a variety of cactus, "contain mescaline which has a hallucinogenic effect when ingested." *Peyote Way Church of God, Inc. v. Thornburgh*, 922 F.2d 1210, 1212 (5th Cir. 1991).[7] The exemption in federal law for the religious use of peyote by members of Indian tribes has

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[6] Respondents fully endorse this holding. *See* Or. Br. in Op. 15 ("the CSA does not contain a 'clear statement' of intent to authorize the Attorney General to determine what uses state-licensed doctors may make of substances that concededly have approved medical uses"); Rasmussen Br. in Op. at 15-18 (same); Patient Br. in Op. 4 (no evidence that Congress, in enacting the CSA, "'intended . . .. to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice'") (quoting letter of June 5, 1998, from Attorney General Reno to Hon. Henry Hyde).

[7] Both peyote and mescaline are classified as Schedule I controlled substances. 21 U.S.C. §§ 812(c), Schedule I (c)(11) (mescaline); Schedule I (c)(12) (peyote); 21 C.F.R. §§ 1308.11(d)(21) (mescaline); 1308.11(d)(23) (peyote) (2004).

led to a flurry of lawsuits by other religious groups challenging, on equal protection and other grounds, the law's failure to include exemptions for the religious use of peyote by non-members of Indiana tribes, *see Peyote Way Church of God, supra*, and the religious use of other drugs, particularly marijuana. *See Olsen v. Drug Enforcement Administration*, 878 F.2d 1458, 1461-64 (D.C. Cir. 1989) (Op. of R. Ginsburg, J.) (Ethiopian Zion Coptic Church), and the cases cited therein);[8] *O Centro Espirita Benficiente Uniao do Vegetal v. Ashcroft*, 342 F.3d 1170, 1186 n.4 (10th Cir. 2003) (rejecting equal protection claim that religious use of *hoasca*, a tea containing dimethyltryptamine, a Schedule I hallucinogen, must be protected because "the Native American Church's use of peyote is protected"), *on reh'g*, 389 F.3d 973 (10th Cir. 2004) (*en banc*), *cert. granted*, April 18, 2005, Docket 04-1084.[9]

The foregoing challenges generally have been rejected.[10] Nevertheless, they reflect efforts by some

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[8] *See also Whyte v. United States*, 471 A.2d 1018 (D.C. Ct. App. 1984) (Rastafarian Church); *Leary v. United States*, 383 F.2d 851, 861 & n.11 (5th Cir. 1967) (individual religious use of marijuana), *rev'd on other grounds*, 395 U.S. 6 (1969).

[9] On rehearing, the Tenth Circuit determined that plaintiffs had shown a probability of success in prevailing on the merits of their claim that the prohibition of the religious use of *hoasca* violates the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.* (2000). 389 F.3d at 976 (*per curiam* op.); *id.* at 1004-1011 (Seymour, J., concurring in part and dissenting in part); *id.* at 1018-31 (McConnell, J., concurring).

[10] *But see Native American Church of New York v. United States*, 468 F.Supp. 1247, 1251 (S.D.N.Y. 1979) (ruling that the regulatory exemption for peyote would have to be made "equally available" to "a bona fide religious organization [that] would make use of peyote for sacramental purposes and regard the drug as a deity"), *aff'd mem. op.*, 633 F.2d 205 (2nd Cir. 1980).

religious groups (and their members) to use the courts to broaden the circumstances under which controlled substances may be used for religious purposes. In light of the Ninth Circuit's decision in this case, however, those efforts may be redirected to state legislatures. The States, of course, may choose to grant religious exemptions to their *own* controlled substances laws. What they have not been able to do, until now, is grant religious exemptions to the Controlled Substances Act. But that is effectively what the court of appeals decision permits, possibly with respect to Schedule I controlled substances (for which there is no recognized medical use), and certainly with respect to controlled substances classified under Schedules II through V. Allowing state law to override federal law with respect to the religious use of controlled substances would undermine "the government's interest in the uniform enforcement of the Controlled Substances Act," an interest "of the highest order." *O Centro Espirita Benficiente Uniao do Vegetal v. Ashcroft*, 389 F.3d at 985 (Murphy, J., concurring in part and dissenting in part). *See also, id.*, at 1031 (Hartz, J., dissenting) (the Government has "a compelling interest in uniform application of the Controlled Substances Act"). Yet that is precisely what the Ninth Circuit's decision allows.

Enhancing Athletic Performance

The abuse of anabolic steroids, a Schedule III controlled substance[11] that "promotes muscle growth," 21 U.S.C. § 802(41)(A) (defining term "anabolic steroid"), has received widespread recent attention in Congressional hearings into the use of steroids in professional sports. *See* House Committee on Government Reform, Hearings on Steroid Use in

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[11] 21 U.S.C. § 812(c), Schedule III(e); 21 C.F.R. § 1308.13(f) (2004).

Sports (ongoing).[12] The hearings have disclosed disturbing details about the extent and seriousness of anabolic steroid abuse. Although anabolic steroids have appropriate medical purposes, *e.g.*, "to treat conditions that occur when the body produces abnormally low amounts of testosterone, such as delayed puberty and some types of impotence," and "to treat body wasting in patients with AIDS and other diseases that result in loss of lean muscle mass,"[13] taking steroids for the purpose of enhancing athletic performance is not one of them. "Inappropriate use of anabolic steroids can have serious health consequences," including, in younger steroid abusers, "[the] risk of permanently halting their growth," in males, "a shrinking of their testicles, reduced sperm count, infertility, baldness, development of breasts, and an increased risk for prostate cancer," and in females, "menstrual abnormalities, deepening of the voice, shrinkage of breasts, male-pattern baldness, and an increase in sex drive, acne, body hair and clitoris size."[14] For both men and women, other consequences include "liver and heart disease, stoke, drug dependence, and increased aggression."[15]

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[12] The statements and written testimony of witnesses at the March 17, 2005, hearing may be found at http://reform.house.gov/GovReform/Hearings/Event Single.aspx?EventID1637. The Committee also heard testimony on April 27, 2005.

[13] Statement of Nora D. Volkow, M.D., Consequences of the Abuse of Anabolic Steroids at 2, Testimony Before the Committee on Government Reform, U.S. House of Representatives, March 17, 2005. Dr. Volkow is the Director of the National Institute on Drug Abuse, National Institutes of Health, United States Department of Health & Human Services.

[14] *Id.* at 3, 9.

[15] *Id.* at 3-4.

In one survey conducted in 2003 by the Centers for Disease Control and Prevention, 6.1% of students in grades 9 through 12 reported illegal use of anabolic steroids at least once in their lifetime, up from 2.7% in 1991; a somewhat differently designed study indicated that 79,000 high school seniors reported having abused anabolic steroids last year (2004).[16] In an attempt to address the problem of steroid abuse, Congress recently enacted the Anabolic Steroid Control Act of 2004, 108 Pub. L. 358, 118 Stat. 1661 (2004), bringing many of the abused substances that previously had not been illegal (particularly steroid precursors) within the scope of the Controlled Substances Act.[17] Other medical and psychiatric testimony underscored the severity of the problem of anabolic steroid abuse.[18]

Under the court of appeals' holding, however, if a State decided to authorize the use of anabolic steroids for purposes which would not generally be regarded as medical in nature, *e.g.*, enhancing athletic performance, body building or weight training, the Attorney General would not be able take any action–civil, administrative or criminal–against registrants who dispensed drugs for those purposes The State's sanctioning of the use of anabolic steroids for such questionable purposes, no matter how unethical or unusual, would effectively bar federal enforcement of the Controlled Substances Act, just as it has with Oregon's use of controlled substances in its experiment with physician-assisted suicide.

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[16] *Id.* at 7.

[17] *Id.* at 6-7.

[18] *See* Statements of Kirk J. Brower, M.D. and Gary I. Wadler, M.D., March 17, 2005

Inducing Euphoria

There is no generally accepted medical use of controlled substances to induce a state of euphoria.[19] Yet, under the Ninth Circuit's holding, if a State decided to authorize physicians to prescribe cocaine and other stimulants for that purpose,[20] the Attorney General would be powerless to take any action against them. In the majority's understanding of the Controlled Substances Act, the States are the ultimate arbiters of what qualifies as a "legitimate medical purpose."

Providing Recreation

No State allows controlled substances to be used for recreational purposes. Any registrant who dispenses controlled substances for such purposes may be prosecuted under the Controlled Substances Act, *see United States v. Henry*, 727 F.2d 1373, 1374 (5th Cir. 1984), *on reh'g*, 749 F.2d 203 (5th Cir. 1984) (*en banc*), and have his federal registration suspended or revoked. Yet, if a State decided to authorize physicians to prescribe controlled substances (*e.g.*, narcotics or barbiturates) for those purposes, the Attorney General would be powerless to take any action any against them.

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[19] By "euphoria," *amicus* means "a sense of intense stimulation, and of psychic and physical well-being." *United States v. Whitley*, 734 F.2d 1129, 1140 (6th Cir. 1984).

[20] Although classified as a narcotic, 21 U.S.C.§ 812(c), Schedule II(a)(4), 21 C.F.R. § 1308.12(b)(4) (2004), cocaine is a stimulant, not a depressant. *See United States v. Whitley*, *supra*, n. 12, 734 F.2d at 1140; *United States v. Castro*, 401 F.Supp. 120, 123 (N.D. Ill. 1975) (noting that, in the pharmacological sense, cocaine is "universally identified with amphetamines," and is "generally considered as an anti-fatigue, anti-soporific stimulant often used to stimulate alertness or euphoria).

Operating Unauthorized Narcotic Drugs Maintenance Programs

The Act authorizes practitioners to dispense narcotic drugs for maintenance treatment. 21 U.S.C. § 823(g) (Supp. 2005). Except in narrowly defined circumstances not involving Schedule II drugs, however, the statute provides "that every practitioner who dispenses narcotics for maintenance treatment must obtain a separate registration, the issuance of which is conditioned upon standards established by the Secretary of Health and Human Services and the Attorney General of the United States." *Luna v. Harris*, 888 F.2d 949, 953 (2nd Cir. 1989). Even with respect to Schedule III, IV and V narcotic drugs, practitioners who dispense drugs to individuals for maintenance treatment must comply with a myriad of statutory and regulatory requirements. *See*, *e.g.*, 21 U.S.C. §§ 823(g)(2)(B)-(D); 21 C.F.R. §§ 1304.03(c), 1304.03(d), 1304.04(f),1304.24, 1304.25, 1306.07(a)(2004). If a practitioner does not have a separate registration to dispense narcotics for maintenance treatment and dispenses Schedule III, IV or V narcotic drugs for such treatment in violation of §§ 823(g)(2)(B)-(D), the Attorney General may, for purposes of § 824(a)(4), "consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section [823(f)] to be inconsistent with the public interest." 21 U.S.C. § 823(g)(2)(E)(i).

Under the court of appeals' holding, a State could effectively nullify the elaborate federal regulatory framework for narcotic drugs maintenance programs by authorizing its own maintenance program without any of the safeguards built into the federal structure. The abuse of unregulated (or inadequately regulated) drug maintenance programs has been well documented. *See Luna*, *supra*, 888 F.2d at 953-54 (noting Congressional concern with the illegal diversion of

methadone used in drug maintenance programs); *United States v. Moore*, 423 U.S. 122, 126 (1975) (noting physician's unorthodox and unapproved method of treating heroin addicts by "saturat[ing]" them with such large quantities of methadone that "heroin would have no [physical] effect" on them and they would develop "a strong psychological desire for detoxification"). *See also Cushing v. Moore*, 783 F.Supp. 727, 729 (N.D.N.Y. 1992) (describing regulatory scheme), *aff'd as modified*, 970 F.2d 1103 (2nd Cir. 1992).

Prior to the court of appeals' decision in this case, it was generally understood that "under the guise of treatment a physician [could not] distribute drugs intended to cater to cravings of an addict." *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) (methadone), citing, *inter alia*, *Jin Fuey Moy v. United States*, 254 U.S. 189, 193 (1920) (morphine sulfate); *Webb v. United States*, 249 U.S. 96, 99-100 (1919) (morphine); *United States v. Behrman*, 258 U.S. 280, 288-89 (1922) (heroin, morphine and cocaine). *See also McBride v. United States*, 225 F.2d 249, 253 (5th Cir. 1955) (codeine). That understanding has been called into question by the Ninth Circuit's opinion.

Conducting Unregulated Research

The Controlled Substances Act allows practitioners to conduct research (including dispensing drugs) with Schedule I controlled substances under strictly defined conditions. The practitioner must be separately registered under the Act; his qualifications and competence must be evaluated by the Secretary of Health and Human Services; and the Secretary must assess the relative merits of the proposed research protocol in consultation with the Attorney General regarding "effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or

scientific use." 21 U.S.C. § 823(f). *See also* 21 C.F.R. §§ 1301.18, 1301.22, 1304.22(c) (2004). Even if the Secretary has deemed the practitioner is qualified to conduct research with Schedule I controlled substances, the Attorney General may deny his registration on one of the grounds specified in § 824(a) of the Act. 21 U.S.C. § 823(f).

Section 824(a)(4) authorizes the Attorney General to suspend or revoke a registration upon a finding that the registrant "has committed such acts as would render his registration under section 823 . . . inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). In determining "the public interest" under § 823, the Attorney General must consider five factors, the last of which is "conduct which may threaten the public health and safety." 21 U.S.C. § 823(f)(5). The court of appeals, however, denied that the Attorney General could suspend or revoke (or deny) "health care practitioners' DEA registrations" solely on this basis. 368 F.2d at 1129.[21] In light of the Ninth Circuit's exegesis of the legislative history, the Attorney General could not refuse to register a practitioner to conduct research with Schedule I controlled substances even if he determined that registration for that purpose would be inconsistent with the public interest because of conduct that might threaten the public health and safety.

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[21] *See also* Or. Br. in Op. 14 ("the 1984 amendments to the CSA [which added the cited language] were not intended to broaden the Attorney General's authority by permitting him to sanction physicians *whose conduct conformed to state laws*") (emphasis added). The legislative history cited by the majority and Oregon, *see* S. Rep. No. 98-225 at 267, 98th Cong., 2nd Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449, does not support this proposition. The requirement that the Attorney General *consider* all five factors does not mean that he must *find* that all five factors are present in order to deny an application for registration or suspend or revoke an existing registration.

Under current law, Schedule I controlled substances may be dispensed only in "federally approved research projects." *Fry v. D.E.A.*, 353 F.2d 1041, 1042 n.1 (9th Cir. 2003-). *See also United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 490 (2001) (for marijuana and other Schedule I controlled substances, "there is but one exception, and it is available only for Government approved research projects"). The court of appeals' crabbed reading of the Attorney General's authority under the Controlled Substances Act, combined with its inappropriate invocation of the "plain statement" rule of *Gregory v. Ashcroft*, effectively overturns the present federal restrictions on research with Schedule I substances.

The Ninth Circuit's holding in this case may be fairly summarized in a single sentence: So long as a controlled substance has *some* legitimate medical purpose, which all substances classified under Schedule II through V do have, a State may authorize its use for *any* purpose, no matter how unethical, unorthodox, untested or unusual, and the Attorney General would be powerless to take any action under the Controlled Substances Act against any registrant who had acted in accord with state law.[22] As the foregoing examples show, the court of appeals' holding would emasculate the Attorney General's authority to enforce the Act in a consistent, principled and uniform manner, and subject federal drug control policy to the vagaries of a patchwork of inconsistent state laws. Such an extraordinary result cannot be one required by a proper interpretation of the Act. The judgment of the court of appeals should be reversed.

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[22] For the reasons explained above, the court's holding even affects the Government's authority to regulate research (including dispensing drugs to human subjects) with Schedule I drugs, for which there is *no* recognized legitimate medical purpose.

CONCLUSION

For foregoing reasons, *amicus curiae*, the Thomas More Society respectfuliy requests that this Honorable Court reverse the judgment of the Court of Appeals.

Respectfully submitted,

Paul Benjamin Linton
Counsel of Record
921 Keystone Avenue
Northbrook, Illinois 60062
(847) 291-3848

Thomas Brejcha
Thomas More Society
29 S. La Salle St. Suite 440
Chicago, Illinois 60611
(312) 782-1680

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39

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IN THE

Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* PRO-LIFE LEGAL DEFENSE FUND, LEGAL CENTER FOR DEFENSE OF LIFE, AND UNIVERSITY FACULTY FOR LIFE IN SUPPORT OF PETITIONERS

RICHARD F. COLLIER, JR.
Collier & Basil, P.C.
100 Thanet, P.O. Box 3720
Princeton, NJ 08543
(609) 924-2213

DWIGHT G. DUNCAN
Counsel of Record
333 Faunce Corner Road
North Dartmouth, MA 02747
(508) 998-9600

COLBE MAZZARELLA
265 Essex Street, Suite 202
Salem, MA 01970
(617) 569-5971

THOMAS M. HARVEY
One Constitution Center
Boston, MA 02129
(617) 886-0364

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

INTEREST OF *AMICI CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 3

I. THE NINTH CIRCUIT'S HOLDING RESTED ON THE ERRONEOUS PREMISE THAT DRUG REGULATIONS ARE A "STATE ISSUE" 3

A. The Federal Government Has Extensively Regulated the Prescription, Distribution, and Utilization of Controlled Substances and Other Drugs For Over One Hundred Years 3

1. The *Import Drugs Act* (1848), *Pure Food and Drugs Act* (1906), and Early Federal Regulations 4

2. The *Federal Food, Drug, and Cosmetic Act* (1938) and New Deal Regulations 7

3. The *Harrison Narcotics Act* (1914) and *Controlled Substances Act* (1970) 9

4. *Durham-Humphrey Amendment* (1951), *Kefauver-Harris Amendments* (1962), and *Medical Device Amendments* (1976) 11

5. Federal Regulations under Ford, Carter, Reagan, Bush, Clinton, and Bush 13

B. The Pervasive Federal Regulation of Controlled Substances and Other Dangerous Drugs Belies Any Claim That This is "State Issue" 15

CONCLUSION 20

TABLE OF AUTHORITIES

CASES:

American Home Prods. Corp. v. Johnson & Johnson, 672 F. Supp. 135 (S.D.N.Y. 1987) 3, 15
F.D.A. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) 8
Grand Labs., Inc. v. Harris, 644 F.2d 729 (8th Cir. 1981) 6
In re Grand Jury Proceedings, 801 F.2d 1164 (9th Cir. 1986) 16
Linder v. United States, 268 U.S. 5 (1925) 16-17
Minneapolis & St. L.R. Co. v. Bombolis, 241 U.S. 211 (1916) 19
Minor v. United States, 396 U.S. 87 (1969) 15, 17
Norfolk S. Ry. Co. v. Kirby, 125 S. Ct. 385 (2004) 18
Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) ..... *passim*
Reina v. United States, 364 U.S. 507 (1960) 15-16, 17
Romero v. International Terminal Operating Co., 358 U.S. 354 (1959) 19
Solid Waste Agency v. U.S. Army Corps of Eng'rs, 531 U.S. 159 (2001) 18
Testa v. Katt, 330 U.S. 386 (1947) 19
United States v. Alveri, 715 F. Supp. 1508 (M.D. Ala. 1989) 15
United States v. Articles of Drug (Lannett), 585 F.2d 575 (3d Cir. 1978) 6
United States v. Darby, 312 U.S. 100 (1941) 17
United States v. Freed, 401 U.S. 601 (1971) 15
United States v. Gel Spice Co., 601 F. Supp. 1214 (E.D.N.Y. 1985) 3
United States v. Kaplan, 895 F.2d 618 (9th Cir. 1990) 10
United States v. Kim, 94 F.3d 1247 (9th Cir. 1996) 16
United States v. Kirk, 70 F.3d 791 (5th Cir. 1995) 19
United States v. Lerebours, 87 F.3d 582 (1st Cir. 1996) 16

United States v. McCoy, 323 F.3d 1114 (9th Cir. 2003) 17
United States v. Moore, 423 U.S. 122 (1975) 10
United States v. New England Grocers Supply Co., 488 F. Supp. 230 (D. Mass. 1980) 3, 15
United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483 (2001) 17, 18
United States v. Rutherford, 442 U.S. 544 (1979) 8, 18
United States v. Rybar, 103 F.3d 273 (3d Cir. 1996) 19
United States v. Tisor, 96 F.3d 370 (9th Cir. 1996) 16
Washington v. Glucksberg, 521 U.S. 702 (1997) 1
Webb v. United States, 249 U.S. 96 (1919) 9
Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973) 8

FEDERAL STATUTES AND REGULATIONS:

Import Drugs Act of 1848, 30 Cong. Ch. 70, 9 Stat. 237 (1848) 3, 4
Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 328 (1902) 4, 6
Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) 3, 4, 5, 6, 7
Virus, Serum & Toxin Act of 1913, Pub. L. No. 66-430, 31 Stat. 828 (1912) (codified at 21 U.S.C. § 151 (2000)) 7
Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785 (1914) (superceded by *Controlled Substances Act* of 1970) . 9, 10
Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301-392 (2000)) 2, 3, 7-8, 11
Durham-Humphrey Amendment of 1951, 82 Cong. Ch. 578, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353 (2000)) 11
Kefauver-Harris Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified in sections of 21 U.S.C. (2000)) 11, 12

Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 9-513, 84 Stat. 236 (1970) (codified at 21 U.S.C. §§ 801-971 (2000)) 10
Controlled Substances Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified at 21 U.S.C. §§ 801-904 (2000)) ..... *passim*
Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 579 (1976) (codified at 21 U.S.C. §§ 360(c)-(k) (2000)) 11, 13
Toxic Substances Control Act of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601-2692 (2000)) 13
Psychotropic Substances Act of 1978, Pub. L. No. 95-633, 92 Stat. 3768 (1978) (codified at 21 U.S.C. § 881 (1994)) 13
Federal Anti-Tampering Act of 1983, Pub. L. No. 98-127, 97 Stat. 838 (1983) (codified at 18 U.S.C. § 1365 (1992)) 14
Dangerous Drug Diversion Control Act of 1984, Pub. L. No. 98-473, 98 Stat. 2070 (1984) (codified at 18 U.S.C. § 1203 (2000)) 14
Narcotics Penalties and Enforcement Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207-2 (1986) (codified in sections 18, 21, and 28 U.S.C. (2000)) 14
Drug Export Amendments Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (1986) (codified at 42 U.S.C. § 262(h)(1)(B)(I) (1994)) 14
Controlled Substances Analogue Enforcement Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207-16 (1986) (codified at 21 U.S.C. §960 (1994)) 14
Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1987) (codified at 21 U.S.C. §381(d) (2000)) 14
Chemical Diversion and Trafficking Act of 1988, Pub. L. No. 100-690, 102 Stat. 4312 (1988) (codified in scattered sections of 21 U.S.C. (1988)) 14

Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified in sections 21 and 42 U.S.C.) 13
Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, 106 Stat. 3547 (1992) (codified at 42 U.S.C. §§ 201, 263(b) (1994) 13
Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2310 (1997) (codified at 21 U.S.C. § 355(d) (1997)) 14
Public Health Security and Bioterrorism Preparedness Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002) (codified in sections of 42 U.S.C.). 14-15
21 C.F.R. § 1306.04(a) 10, 18

ARTICLES, BOOKS, AND TREATISES:

25 American Jurisprudence 2d *Drugs and Controlled Substances* (2004) 15
Berger, Mitchell & Berger, Barry, *FDA Overview, available at* eMedicine.com (2003) 5, 6, 8, 12, 14
Greenberg, Martin Alan, *Prohibition Enforcement: Charting a New Mission* (1999) 9, 11
Heath, Wesley J., *America's First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 Food & Drug L.J. 169 (2004) 4, 5
Hull, Richard T., "Medical Ethics and Society," *available at* http://www.richard-t-hull.com/publications/medical_ethics.pdf (1987) 5
Hutt, Peter, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 Food & Drug L.J. 101 (1995) 18
Jackson, Charles O., *Food and Drug Legislation in the New Deal* (1970) 7
Klein, Daniel B. & Tabarrok, Alexander, *History of Federal Regulation: 1902-Present, available at* www.fdareview.org/history (2001) ..... *passim*

Korwek, Edward L., *Human Biological Drug Regulation*, 50 Food & Drug L.J. 123 (1995)..... 7
Law, Marc T., *History of Food and Drug Regulation in the United States*, *EH.Net Encyclopedia* (Whaples, Robert ed.) (2004)..... 4, 5, 6, 12
Merrill, Richard A. & Hutt, Peter Barton, *Food and Drug Law* (1980)..... 11
Walsh, Charles J. & Pyrich, Alissa, *Rationalizing the Regulation of Prescription Drugs and Medical Devices*, 48 Rutgers L. Rev. 883 (1996).... 5-6, 7, 11, 13

INTEREST OF *AMICI CURIAE* [1]

The Pro-Life Legal Defense Fund, Inc. (PLLDF), a Massachusetts not-for-profit corporation, and the Legal Center for Defense of Life, Inc. (the "Legal Center"), a New Jersey not-for-profit corporation, both provide *pro bono* legal services for the protection of human life. University Faculty for Life (UFL) is a multidisciplinary association of scholars founded in 1989 to promote research, dialogue, and scholarship among faculty members on various topics in medical ethics including euthanasia. The PLLDF, Legal Center, and UFL strongly oppose the use of federally-regulated controlled substances to facilitate physician-assisted suicide, euthanasia, or eugenics. *Amici* respectfully submit this brief in support of the Petitioners and urge the Court to reverse the Ninth Circuit.

The PLLDF and Legal Center filed a joint brief, as friends of this Court, in *Washington v. Glucksberg*, 521 U.S. 702 (1997). *See* 1996 WL 656314. Here, as in *Glucksberg*, *amici*'s purpose in filing is to correct the historical errors of the Ninth Circuit's majority opinion. In *Glucksberg*, *amici* respectfully pointed out that the Ninth Circuit's "majority opinion distort[ed] the historical record in an apparent attempt to justify its creation of a new fundamental constitutional right." *Id.* at *5. Similarly, *amici* now respectfully point out that the Ninth Circuit's majority opinion has distorted the historical record of federal regulation of medicine and controlled substances in an apparent attempt to characterize this case as involving an exclusively "state issue." Because the Ninth Circuit based its holding on this erroneous premise, that court should once again be reversed.

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[1] Counsel for all four parties have consented to the filing of this *amicus* brief. Their consent letters are on file with the Clerk of the Court. No counsel for a party authored this brief in whole or in part.

SUMMARY OF ARGUMENT

The federal government has extensively regulated the practice of medicine and the distribution of controlled substances for over one hundred years. This longstanding and pervasive federal regulation belies any claim that this case involves an exclusively "state issue." As a result, the Ninth Circuit, which based its holding on the erroneous premise that controlled substances constitute "an area of law traditionally reserved for state authority," should be reversed.

An examination of the history of federal drug regulation demonstrates the Ninth Circuit's error. Interest in federal drug regulation arose contemporaneously with the interest in state regulation during the late nineteenth century. Congress provided the first comprehensive drug regulations in the *Pure Food and Drugs Act* of 1906 and delegated even greater authority to federal regulators under the *Federal Food, Drug, and Cosmetic Act* of 1938 (FFDCA). The FFDCA also established the precursor to the FDA, which now regulates one-quarter of the gross national product.

Moreover, Congress has regulated highly dangerous drugs extensively since the *Harrison Narcotics Act* of 1914. To provide even greater federal oversight, Congress passed the *Controlled Substances Act* of 1970 (CSA). The CSA is just one of over fifty pieces of legislation since 1914 pursuant to which federal agencies have enacted regulations governing controlled substances.

Federal regulations thus provide comprehensive and uniform standards for prescribing, dispensing, and using controlled substances and other dangerous drugs. Against this extensive regulatory background, a state cannot unilaterally decide to "opt out" of federal regulations. Allowing such an unprecedented circumvention of federal law for every state that disagrees with a federal policy would not only be antithetical to the Congressional objective of protecting public health and safety in this case, but also create an impracticable system of administrative law by establishing a precedent for future opt-outs.

ARGUMENT

I. THE NINTH CIRCUIT'S HOLDING RESTED ON THE ERRONEOUS PREMISE THAT DRUG REGULATIONS ARE A "STATE ISSUE."

The decision of the Ninth Circuit should be reversed because the majority's opinion failed to recognize that the federal government has regulated the practice of medicine and distribution of drugs extensively. The premise of the Ninth Circuit's opinion—that drug regulations involve "an area of law traditionally reserved for state authority"—is incorrect as a matter of both historical and current practice. For over one hundred years the federal government has regulated the prescription, distribution, and utilization of controlled substances and other dangerous drugs. The extensive federal regulation of this area of law thus belies any claim that this case involves an exclusively "state issue."

A. The Federal Government Has Extensively Regulated the Prescription, Distribution, and Utilization of Controlled Substances and Other Drugs For Over One Hundred Years.

Federal regulations have governed this area of medicine for over one hundred years and continue to do so today.[2] The *Import Drugs Act* (1848), *Pure Food and Drugs Act* (1906), *Harrison Narcotics Act* (1914), *Federal Food, Drug, and Cosmetic Act* (1938), and *Controlled Substances Act* (1970) are just a few of the many statutes under which

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[2] *See American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) ("Federal regulation of drug safety and efficacy is pervasive and complete."); *United States v. Gel Spice Co.*, 601 F. Supp. 1214, 1229 (E.D.N.Y. 1985) (noting the "pervasive nature of the federal regulation of the food and drug industry"); *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230, 238 (D. Mass. 1980) (basing its holding on the "pervasive nature and long history of federal regulation of the food and drug industry").

executive agencies have established myriad regulations. The comprehensiveness of this federal regulatory system demonstrates the federal government's substantial and longstanding interest in protecting public health and maintaining public safety with regard to controlled substances and other dangerous drugs.

1. The *Import Drugs Act* (1848), *Pure Food and Drugs Act* (1906), and Early Federal Regulations

The "interest in federal regulation [of food and drugs] arose contemporaneously with interest in state regulation" during the late nineteenth century. Marc T. Law, *History of Food and Drug Regulation in the United States*, at 4 (2004). During the Reconstruction years, Congress established the U.S. Department of Agriculture Bureau of Chemistry, the predecessor to the Food and Drug Administration (FDA). Early federal regulations regarding the prescription, distribution, and utilization of drugs targeted specific issues of national importance such as importation and biologics. *See, e.g.*, *Import Drugs Act* of 1848, 30 Cong. Ch. 70, 9 Stat. 237 (1848) (curbing the import of adulterated medicines); *Biologics Control Act* of 1902, Pub. L. No. 57-244, 32 Stat. 328 (1902) (requiring the federal government to grant pre-market approval for every biological drug and for the process and facility producing such drugs).[3]

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[3] *See also* Wesley J. Heath, *America's First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 Food & Drug L.J. 169, 199 (2004) ("Defeating critics who had argued that the federal government should not interfere with freedom of commerce, the [*Import Drugs Act* of 1848] had proven not only that regulation of some markets could be extremely beneficial but also that the federal government was a highly competent drug regulator. The 1848 law undoubtedly contributed greatly to Congress' confidence in the federal government's ability to regulate drugs.").

Before the emergence of a comprehensive federal regulatory system in 1906, most "[d]rugs could be bought and sold like any other consumer good." Mitchell S. Berger & Barry A. Berger, *FDA Overview, Introduction: History of Food and Drug Regulation*, at *1 (2003); *see also* Richard T. Hull, "Medical Ethics and Society," at *4 (1987) ("[T]here was virtually no regulation of medicines and remedies. Medicines containing narcotics, such as morphine and cocaine, were sold without restriction. Quack remedies—some claiming to cure cancer—and contaminated drugs were largely uncontrolled by the federal government.").

As a result, in the late nineteenth century, national interest grew in establishing a general and comprehensive system for regulating food and drugs. *See* Heath, *supra*, at 170 ("As continued industrialization and social change swept the nation throughout the later half of the nineteenth century, the federal government had no choice but to deconstruct its ad hoc governmental system and replace it with broad institutional structures."). By 1906, America was "ready for comprehensive drug regulation." *Id.* at 199.

Thus, following a long legislative battle,[4] Congress passed the *Pure Food and Drugs Act* of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906). The 1906 Act provided the statutory authorization necessary for a comprehensive system of food and drug regulation at the federal level. *See* Law, *supra*, at *1 ("Federal regulation of the industry began on a large scale in the early twentieth century when Congress enacted the Pure Food and Drugs Act of 1906.").

The 1906 Act "banned the manufacture and distribution of adulterated and misbranded food and drugs" and prohibited "false and misleading advertising of food and drugs." Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices*, 48

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[4] *See* Law, *supra*, at *4 (noting that "conflict among competing interest groups regarding the provisions of a federal law made it difficult to build an effective political constituency").

Rutgers L. Rev. 883, 891 (1996). Violation of the Act could result in "seizure of non-conforming goods or criminal penalties against those responsible for the violation." *Id.* The Act also recognized both the *U.S. Pharmacopoeia*, (established in 1820) and *National Formulary* (originally published in 1888) as "official standards for the strength, quality, and purity of drugs and for the tests to make such determinations." Daniel B. Klein & Alexander Tabarrrok, *History of Federal Regulation: 1902-Present*, at *2 (2001). As a result, the 1906 Act established the first comprehensive system of drug regulations and set the stage for future federal regulations. *See United States v. Articles of Drug (Lannett)*, 585 F.2d 575, 577 (3d Cir. 1978) ("Federal regulation of the drug industry may be traced to the passage of the Pure Food and Drug Act of 1906.").[5]

At the same time, Congress also turned its attention to establishing federal regulations for biological drugs. Federal regulation of human biologics began in 1902 when Congress enacted the *Biologics Control Act*, Pub. L. No. 57-244, 32 Stat. 328 (1902). The Act required that the federal government grant premarket approval for every biological drug and for every process and facility producing such drugs. *See Grand Labs., Inc. v. Harris*, 644 F.2d 729, 732 (8th Cir. 1981) (stating that the Act "prohibit[ed] the importation or interstate shipment of any virus, serum, toxin, antitoxin, or analogous products unless licensed by the Treasury

[5] Responsibility for enforcing the *Pure Food and Drugs Act* of 1906 fell to the Bureau of Chemistry, a division of the United States Department of Agriculture (USDA), which conducted some of earliest studies regarding food and drugs in the United States. The USDA's Division of Chemistry was established by President Abraham Lincoln in 1862. In 1901 the Division became the Bureau of Chemistry, which in 1927 became the Food, Drug and Insecticide Administration, which subsequently became the FDA in 1931. *See* Law, *supra*, at *5. The FDA currently regulates products accounting for approximately twenty-five percent of the United States gross national product, has over nine thousand employees, and has a total budget of over $1.4 billion. *See* Berger & Berger, *supra*, at *1, 6.

Department and properly labeled."). In 1913, Congress amended the 1902 Act by passing the *Virus, Serum & Toxin Act* of 1913, Pub. L. No. 66-430, 31 Stat. 828 (1912). As a result, the federal regulation of biological drugs, like the regulation of other drugs under the *Pure Food and Drugs Act* of 1906, was well-established even prior to the First World War. *See* Edward L. Korwek, *Human Biological Drug Regulation*, 50 Food & Drug L.J. 123, 124 (1995) (pointing out the "long history of biologics regulation, beginning in 1902 with the Virus, Serum, and Antitoxin Act" and noting that "such a ninety-year history, even with an emphasis on the last fifty years, cannot be easily reduced to a few pages of text").

2. The *Federal Food, Drug, and Cosmetic Act* (1938) and New Deal Regulations

The federal regulation of food and drugs continued to increase significantly during the New Deal. *See generally* Charles O. Jackson, *Food and Drug Legislation in the New Deal* (1970). During the early 1930s, Congress "weighed and rejected several bills aimed at improving existing federal regulation of drugs." Walsh & Pyrich, *supra*, at 893. In 1937, however, over one hundred people (mostly children) died as the result of ingesting a drug known as Elixir Sulfanilamide. The public outcry over the incident "spurred Congress to undertake the necessary process of reforming federal drug law." *Id.*; *see also* Klein & Tabarrok, *supra*, at *3 (noting that the Elixir Sulfanilamide tragedy demonstrated to Congress that "unfettered markets cause reckless injury and that public safety called for additional laws").

As a result, in 1938 Congress strengthened the federal government's power to protect the public from dangerous drugs by enacting the *Federal Food, Drug, and Cosmetic Act* of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified

at 21 U.S.C. §§ 301-392 (2000)). This Court has described the 1938 Act's pervasive reach and severe penalties:

> The 1938 Act, which established a system of premarketing clearance of drugs, prohibited the introduction into commerce of any "new drug" unless a new drug application (NDA) filed with the Food and Drug Administration (FDA) was effective with respect to that drug. . . . The Government could sue to enjoin violations, prosecute criminally, and seize and condemn the articles.

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 612-613 (1973); *see also F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) ("[T]he Act generally requires the FDA to prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'") (quoting *United States* v. *Rutherford*, 442 U.S. 544, 556 (1979)).[6]

Thus, under the *Federal Food, Drug, and Cosmetic Act* of 1938, the federal government was "given considerably greater authority over the food and drug industry." Law, *supra*, at *6; *see also* Klein & Tabarrok, *supra*, at *4 (pointing out that because of the broad construction the courts have given to the interstate commerce clause, "in practice the [Act] regulates every drug"). The

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[6] *See also* Berger & Berger, *supra*, at *2 ("Among other things, the 1938 Act did the following: compelled manufacturers to demonstrate to the FDA the safety of new drugs prior to marketing; allowed the FDA to inspect manufacturing facilities; set tolerances for certain substances such as pesticides; extended FDA regulation to color additives and cosmetics; allowed the FDA to seek injunctions from courts; and provided detailed legal definitions of drug, devices, cosmetics, and labeling.").

"developments of this early period set a precedent for federal government activism in medicine." *Id.* at 3.

3. The *Harrison Narcotics Act* (1914) and *Controlled Substances Act* (1970)

The comprehensive federal regulation of narcotics, controlled substances, and other highly dangerous drugs began (but certainly did not end) with the *Harrison Narcotics Act* of 1914, Pub. L. No. 63-223, 38 Stat. 785 (1914). Indeed, according to a 1970 Congressional report: "Since 1914 the Congress has enacted more than fifty pieces of legislation relating to control and diversion, from legitimate channels, of those drugs referred to as narcotic and dangerous drugs." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1971 U.S.C.C.A.N. 4566, 4601. The provisions of the *Harrison Act* and subsequent legislation were consolidated in the *Controlled Substances Act* of 1970.

Congress enacted the *Harrison Narcotics Act* of 1914 to limit the distribution of cocaine and heroin to health care professionals and to regulate the free use that had been in effect prior to the statute. *See* Klein & Tabarrrok, *supra*, at *3 ("The *Harrison Narcotics Act* of 1914 placed a tax on the production, sale, and use of opium and required prescriptions for products exceeding the allowable limit of narcotics. This act also mandated increased record keeping for physicians and pharmacists who dispense narcotics."). In 1919, the Supreme Court expansively interpreted the *Harrison Act* to prohibit any distribution of these drugs and held that such distribution was criminal. *See Webb v. United States*, 249 U.S. 96, 99-100 (1919).

The *Harrison Narcotics Act* of 1914 became the foundation for the federal regulation of controlled substances and dangerous drugs. *See* Martin Alan Greenberg, *Prohibition Enforcement* 6 (1999) ("For more than 50 years, this federal statute was the main basis of narcotics regulation in the U.S. as interpreted by the Supreme Court.").

Congress, however, continued to enact legislation—over fifty statutes between 1914 and 1970—to provide even more federal oversight of narcotics and controlled substances. *See* H.R. Rep. No. 91-1444 (1970), *reprinted in* 1971 U.S.C.C.A.N. 4566, 4601.

The laws and various amendments related to the *Harrison Narcotics Act* were consolidated and reinforced in the *Comprehensive Drug Abuse Prevention and Control Act* of 1970, Pub. L. No. 9-513, 84 Stat. 236 (1970). As Title II of this Act, Congress enacted the *Controlled Substances Act* (CSA), 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified at 21 U.S.C. §§ 801-904 (2000), under which it is "unlawful to prescribe or dispense controlled substances without a federal registration." *Oregon v. Ashcroft*, 368 F.3d 1118, 1121 (9th Cir. 2004) (citing 21 U.S.C. § 841(a)(1)).

The CSA prohibits physicians from dispensing and prescribing controlled substances except for legitimate medical purposes. *See* 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose."); *United States v. Moore*, 423 U.S. 122, 124 (1975) (holding that physicians violate the CSA "when their activities fall outside the usual course of professional practice"); *United States v. Kaplan*, 895 F.2d 618, 619 (9th Cir. 1990) (stating that the CSA prohibits "prescribing controlled substances for reasons other than legitimate medical purposes").

Moreover, as the Ninth Circuit's majority admits, "[i]n 1984, Congress amended the CSA to give broader authority to the Attorney General" in a provision that "gives the Attorney General new discretion over the registration of health care practitioners." *Ashcroft*, 368 F.3d at 1122. "The Attorney General is now authorized to revoke a physician's prescription privileges upon his determination that the physician has 'committed such acts as would render his registration . . . inconsistent with the public interest[.]'" *Id.* (citing 21 U.S.C. § 824(a)(4)). Overall, the *Controlled Substances Act* significantly enhanced federal regulatory

power because it reflected a "fundamental change in interpretation of the [C]ommerce [C]lause of the Constitution, thus eliminating the need to portray a police function as a revenue measure." Greenberg, *supra*, at 6.

4. *Durham-Humphrey Amendment* (1951), *Kefauver-Harris Amendments* (1962), and *Medical Device Amendments* (1976)

Meanwhile, federal regulation of those drugs regulated under the *Federal Food, Drugs, and Cosmetic Act* of 1938 continued during the post-World War II years.[7] Indeed, since its enactment, "the 1938 Act has been amended more than twenty times." Walsh & Pyrich, *supra*, at 896. The general trend in amendments to the Act has been to "increase the coverage of the Act or to increase the substantive authority granted to the FDA over products already within its jurisdiction." *Id.* at 896 n.35 (citing Richard A. Merrill & Peter Barton Hutt, *Food and Drug Law* 5 (1980)). Among the most significant reforms were the *Durham-Humphrey Amendment* of 1951, the *Kefauver-Harris Amendments* of 1962, and the *Medical Device Amendments* of 1976. *See id.* ("These revisions laid the final building blocks for the comprehensive system of drug and medical device regulation that exists today.").

Disagreements over whether certain drugs required a physician's prescription led to the *Durham-Humphrey Amendment* of 1951, 82 Cong. Ch. 578, 65 Stat. 648 (1951). The *Durham-Humphrey Amendment* permitted a drug to be sold directly to patients "unless, because of its toxicity or other potential for harmful effect or because the method of

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[7] *See* Klein & Tabarrok, *supra*, at *5 ("In the post-World War II era, the field of pharmacology entered a new age. People with bacterial illnesses could now be treated with a host of new antibiotics, and diabetics were likewise given the life-saving invention of insulin. In the 1950s in particular, many new drugs were called 'magic bullets' because of their potency and swift defeat of disease. The very success of the new drugs, however, spurred new regulations.").

collateral measures necessary to its use, it may be sold and used only under the supervision of a practitioner." Law, *supra*, at *6-7. The 1951 Act thus delineated a clearer distinction between prescription and over-the-counter drugs, and, under federal law, "[m]any important drugs could be sold only by prescription from a licensed practitioner." Klein & Tabarrok, *supra*, at *5.

The "most significant expansion" in FDA authority over drugs in this period, however, occurred when Congress enacted the *Kefauver-Harris Amendments* of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962). Law, *supra*, at *7. In response to the thalidomide birth-defect tragedy,[8] Congress passed the *Kefauver-Harris Amendments*, which "require[d] drug companies to conduct and submit tests determining safety and efficacy." Klein & Tabarrok, *supra*, at *6. In addition, federal regulators now had to "preclear all human trials, drug advertising, and labeling." *Id.*[9]

In the post-World War II era, the federal regulation of medical devices also became a prominent issue. *See* Klein & Tabarrok, *supra*, at *7 ("As with drugs, the field of medical devices entered a new era after World War II."). As medical devices became "more common and more complex," it

[8] *See* Klein & Tabarrok, *supra*, at *6 (describing how the West German pharmaceutical thalidomide, which by 1962 had been sold in forty-six countries (although not the United States), caused severe birth defects, including truncated limbs, in thousands of newborn babies).

[9] *See also* Berger & Berger, *supra*, at *3 ("Among other things, the amendment requires drug manufacturers to show the effectiveness of their products as well as their safety, to report adverse events to the FDA, and to ensure that their advertisements to physicians disclose the risks as well as the benefits of their products. Informed consent was required from participants in clinical studies. The FDA also was given jurisdiction over prescription drug advertising. In addition, the agency was required to approve a regulatory submission known as a new drug application before a company could market a new drug and be allowed to issue good manufacturing practice guidelines governing how drugs were to be manufactured. Inspection of drug manufacturers was mandated every 2 years.").

became apparent "that some sort of federal safety regulation was necessary." Walsh & Pyrich, *supra*, at 902. In response, Congress passed the *Medical Device Amendments* of 1976, Pub. L. No. 94-295, 90 Stat. 579 (1976) to provide a comprehensive and uniform system of federal regulation over medical devices. With the passage of the *Medical Device Amendments*, federal regulators "achieved jurisdiction over nearly every commercial implement or substance used in the treatment or diagnosis of disease." Walsh & Pyrich, *supra*, at 903. The federal government has continued to regulate medical devices extensively to ensure public health and safety. *See, e.g.*, *Safe Medical Devices Act* of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (substantially increasing reporting requirements for medical devices); *Mammography Quality Standards Act* of 1992, Pub. L. No. 102-539, 106 Stat. 3547 (1992) (ensuring that mammography facilities are certified and inspected).

5. Federal Regulations Under Ford, Carter, Reagan, Bush, Clinton, and Bush

Following the *Controlled Substances Act* of 1970, Congress continued to regulate controlled substances and other dangerous drugs under both the Ford and Carter administrations. *See, e.g.*, *Toxic Substances Control Act* of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (requiring premarket notification for chemical substances); *Psychotropic Substances Act* of 1978, Pub. L. No. 95-633, 92 Stat. 3768 (1978) (controlling illicit trafficking of psychotropic substances across national borders); *see also Medical Device Amendments* of 1976, Pub. L. No. 94-295, 90 Stat. 579 (1976). However, it was under the Reagan administration (despite its proclivity for deregulation) that Congress enacted a number of new statutes that further

extended the already pervasive federal oversight of controlled substances and other drugs.[10]

Likewise, under President Clinton, Congress attempted to modernize drug regulation through the *Food and Drug Modernization Act* of 1997, Pub. L. No. 105-115, 111 Stat. 2310, § 115(a) (1997). The *Food and Drug Modernization Act* established "fast-track approval for certain new drugs and accelerated approval for innovative devices by exempting certain devices from premarket notification requirements." Berger & Berger, *supra*, at 5. The Act also allowed federal regulators "to use expert panels in the drug approval process, regulated health claims in food, reauthorized [a previous prescription drug statute], and provided additional marketing exclusivity time to companies that conducted pediatric studies." *Id.* at 5-6.

As the United States entered the twenty-first century, the importance of federal regulation over controlled substances and other drugs was made frighteningly clear. In response to the attacks of September 11, 2001 and the subsequent anthrax scares, Congress enacted the *Public Health Security and Bioterrorism Preparedness Act* of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002). The *Bioterrorism Act* provides federal regulators with "significant new authority" for regulating the nation's food and drug supply. Berger & Berger, *supra*, at *61.

Overall, the comprehensive federal regulation of controlled substances and other drugs from the *Food and Drug Act* of 1906 to the *Public Health Security and*

[10] *See, e.g.*, *Federal Anti-Tampering Act* of 1983, Pub. L. No. 98-127, 97 Stat. 838 (1983); *Dangerous Drug Diversion Control Act* of 1984, Pub. L. No. 98-473, 98 Stat. 2070 (1984); *Narcotics Penalties and Enforcement Act* of 1986, Pub. L. No. 99-570, 100 Stat. 3207-2 (1986); *Controlled Substances Analogue Enforcement Act* of 1986, Pub. L. No. 99-570, 100 Stat. 3207-16 (1986); *Drug Export Amendments Act* of 1986, Pub. L. No. 99-660, 100 Stat. 3743, §351(h)(I)(B)(i) (1986); *Prescription Drug Marketing Act* of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1987); *Chemical Diversion and Trafficking Act* of 1988, Pub. L. No. 100-690, 102 Stat. 4312 (1988).

Bioterrorism Preparedness Act of 2002 demonstrates not only the extent but also the importance of uniform federal regulations in protecting public health and safety. Indeed, the "pervasive nature and long history of federal regulation of the food and drug industry" are undeniable. *New England Grocers Supply Co.*, 488 F. Supp. at 238; *see also American Home Prods. Corp.*, 672 F. Supp. at 145 ("Federal regulation of drug safety and efficacy is pervasive and complete.").

B. The Pervasive Federal Regulation of Controlled Substances and Other Dangerous Drugs Belies Any Claim That This is a "State Issue."

The comprehensive federal regulations described above belie any claim that this case involves "an area of law traditionally reserved for state authority." *Ashcroft*, 368 F.3d at 1125. Indeed, federal drug regulations provide uniform standards for prescribing, dispensing, and using controlled substances. As a result, a State cannot "opt out" of federal drug regulations. Allowing such a circumvention of federal law would set a dangerous precedent for future opt-outs.

It is black-letter law that "[w]ith regard to federal regulation, Congress undoubtedly possesses the authority to proscribe drugs it considers dangerous to the public welfare." 25 Am. Jur. 2d *Drugs and Controlled Substances* § 19 (2004); *see also United States v. Alveri*, 715 F. Supp. 1508, 1511 (M.D. Ala. 1989) ("To paraphrase Justice Douglas's rationale in *Freed*, one would hardly be surprised to learn that dispensation of drugs is an act involving substantial governmental concerns. . . . [T]his is Congress's legitimate prerogative.") (citing *United States v. Freed*, 401 U.S. 601, 609 (1971)).

This Court has repeatedly upheld federal regulation of the distribution of controlled substances as within Congress's Commerce Clause authority. *See Minor v. United States*, 396 U.S. 87, 98 n.13 (1969) (ban on sale of narcotics is within Congress's constitutional power); *Reina v. United*

States, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws"); *see also United States v. Tisor*, 96 F.3d 370, 375 (9th Cir. 1996), ("Controlled Substances Act does not exceed Congressional authority under Commerce Clause."); *United States v. Kim*, 94 F.3d 1247, 1250 (9th Cir. 1996) ("[E]very circuit that has considered a Commerce Clause challenge to § 841(a)(1) after *Lopez* has upheld the provision's constitutionality.").

Moreover, it is also black-letter law that Congress does "not abridge the reservation of police powers to the states under the Tenth Amendment by passing statutes prohibiting the possession and distribution of drugs." 25 Am. Jur. 2d *Drugs and Controlled Substances* § 19 (2004). *See Reina*, 364 U.S. at 511 (rejecting argument that state narcotic laws are "a subject that has traditionally been within the police power of the state" because "[t]he relevant inquiry here" is simply whether the federal action is "necessary and proper to the more effective enforcement of the undoubted power to enact the narcotics laws").[11]

As Judge Wallace's dissent makes clear, the majority's "argument that '*direct* control of medical practice in the states is beyond the power of the federal government' misses the point." *Ashcroft*, 368 F.3d at 1143 (quoting *Linder v. United States*, 268 U.S. 5 (1925)).[12] Both the Supreme Court

[11] *See also United States v. Lerebours*, 87 F.3d 582, 585 (1st Cir. 1996) (rejecting defendant's Tenth Amendment police powers argument because "courts will not strike down a statute under the Tenth Amendment where Congress was within its powers under the Commerce Clause to enact the statute"); *In re Grand Jury Proceedings*, 801 F.2d 1164, 1169 (9th Cir. 1986) (per curiam) (rejecting Tenth Amendment argument that the "control of medical practice is beyond the power of the federal government" because "the Commerce Clause empowers the federal government to regulate prescription drugs" and thus "physician may not defend a federal prosecution for improper drug prescription practices on Tenth Amendment grounds").

[12] The Ninth Circuit's reliance on *Lochner*-era cases to justify an unprecedented regulatory "opt out" right for individual states is entirely misplaced. The majority cited *Linder* as establishing a constitutional

and Ninth Circuit's "binding precedent compel the conclusion that Congress acts comfortably within its Commerce Clause power when it regulates the prescription and dispensation of controlled substances." *Id.* at 1143 (citing *Minor*, 396 U.S. 87, and *Reina*, 364 U.S. 507). Because "Congress' Commerce Clause power to prohibit physicians from prescribing controlled substances to assist suicide is not open to serious question[,] [t]hat ends the matter in this circuit and, of course, for this case." *Id.* at 1142 (citing *United States v. McCoy*, 323 F.3d 1114 (9th Cir. 2003)).

Indeed, respondents do not (and cannot) cite to a single currently-applicable case that would suggest there is a constitutional limitation on Congress's ability to exercise the full scope of its enumerated powers simply because it may have some effect on the practice of medicine. In fact, directly contrary to the respondents' assertions, this Court has applied the *Controlled Substances Act* in cases where its impact on the practice of medicine and state law was obvious without intimating the existence of any such constitutional limitation. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 494-495 (2001) (*Controlled Substances Act* precludes recognition of a "medical necessity" defense for marijuana use despite California's determination that marijuana has medical utility); *Moore*, 423 U.S. at 139 (upholding *Controlled Substances Act* conviction of physician for illegally dispensing controlled substances from his medical practice).

Thus, because controlled substances are *not* "an area of law traditionally reserved for state authority" (see *supra* Part

prohibition against Congress's legislating in a way that affects "control of medical practice in the states." *Ashcroft*, 368 F.3d at 1124. However, *Linder*'s reliance on the *Lochner*-era doctrine that Congress could not employ its enumerated powers to accomplish general goals relating to health and welfare was expressly disavowed in *United States v. Darby*, 312 U.S. 100, 115-117 (1941) and has not been revived since.

I.A.1-I.A.5) and because the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) does not "invoke[] the outer limits of Congress' power" or "push the limit of congressional authority" under the Commerce Clause, *Solid Waste Agency v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172-173 (2001), the "clear statement rule does not apply" and this Court should evaluate the Attorney General's Directive "according to ordinary standards of deference." *Ashcroft*, 368 F.3d at 1143 (Wallace, J., dissenting).

United States v. Rutherford, 442 U.S. 544 (1979), also offers an instructive comparison. In holding that terminally ill cancer patients could not enjoin the United States from interfering with the interstate shipment and sale of Laetrile, Justice Marshall, writing for the Court, stated that "the construction of a statute by those charged with its administration is entitled to substantial deference." *Id.* at 553; *see id.* at 559 ("Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.").[13]

The Court pointed out that "[s]uch deference is particularly appropriate where, as here, an agency's interpretation involves an issue of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives." *Id.* at 554 (citations omitted). Justice Marshall concluded that "historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise." *Id.* at 558.

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[13] *See also Oakland Cannabis Buyers' Coop.*, 532 U.S. at 491 n.4 (noting that "[e]limination of medical-necessity defense under Controlled Substances Act . . . does not require an explicit statement in the Act, as the Supreme Court will decline to set the bar so high, considering that . . . such a defense would entail a social balancing that is better left to Congress"); *cf.* Peter Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 Food & Drug L.J. 101, 103 (1995) ("Administration of the Act is and always has been largely a matter of judgment and discretion.").

Similarly, under the *Controlled Substance Act*, Congress has established comprehensive and uniform standards for the distribution of controlled substances and other dangerous drugs. These comprehensive and uniform standards are essential for the effective regulation of drugs in all fifty states. *See United States v. Rybar*, 103 F.3d 273, 284 (3d Cir. 1996) ("[F]ederal regulation of controlled substances [is] 'essential to effective control of the interstate incidents' of traffic in particular commodities.") (quoting *United States v. Kirk*, 70 F.3d 791, 796-797 (5th Cir. 1995)); c*f. Norfolk S. Ry. Co. v. Kirby*, 125 S. Ct. 385, 396 (2004) (O'Connor, J.) (citing *Romero v. International Terminal Operating Co.*, 358 U.S. 354, 373 (1959) ("[S]tate law must yield to the needs of a uniform federal maritime law when this Court finds inroads on a harmonious system[,] [b]ut this limitation still leaves the States a wide scope.").[14]

It is clear, however, that neither Oregon, nor any other state, may decide unilaterally to "opt out" of comprehensive and uniform federal regulations. *Cf. Testa v. Katt*, 330 U.S. 386, 393 (1947) (concluding that a state cannot "refuse to enforce the right arising from the law of the United States because of conceptions of impolicy or want of wisdom on the part of Congress in having called into play its lawful powers") (quoting *Minneapolis & St. L.R. Co. v. Bombolis*, 241 U.S. 211, 222 (1916)); *id.* at 391 ("[T]he Constitution and the laws passed pursuant to it are the supreme laws of the land, binding alike upon states, courts, and the people, 'anything in the Constitution or Laws of any State to the contrary notwithstanding.'") (quoting U.S. Const. Art. VI, § 2). Allowing such an unprecedented circumvention of federal law for any state that disagrees with a federal policy

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[14] Indeed, in this case, as Judge Wallace has pointed out, "[s]tate legislators may supplement the [Attorney General's] sanctions, and they may authorize alternative methods for assisting suicide that do not involve the prescription of controlled substances." *Ashcroft*, 368 F.3d at 1148.

would not only be antithetical to the Congressional objective of protecting public health and safety in this case, but also create an impracticable system of administrative law by establishing a dangerous precedent for future opt-outs.

CONCLUSION

For the foregoing reasons, the decision of the Ninth Circuit should be reversed.

Respectfully submitted,

RICHARD F. COLLIER, JR.
Collier & Basil, P.C.
100 Thanet, P.O. Box 3720
Princeton, NJ 08543
(609) 924-2213

DWIGHT G. DUNCAN
Counsel of Record
333 Faunce Corner Road
North Dartmouth, MA 02747
(508) 998-9600

COLBE MAZZARELLA
265 Essex Street, Suite 202
Salem, MA 01970
(617) 569-5971

THOMAS M. HARVEY
One Constitution Center
Boston, MA 02129
(617) 886-0364

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No. 04-623

IN THE

Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

STATE OF OREGON, ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF *AMICUS CURIAE* FOR THE NATIONAL ASSOCIATION OF PRO-LIFE NURSES IN SUPPORT OF PETITIONERS

DANIEL AVILA
Counsel of Record for the Amicus
31 Linden Street
Everett, Massachusetts 02149
(617) 387-3049

Dated: May 9, 2005

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

TABLE OF CONTENTS

INTEREST OF AMICUS CURIAE.....1

SUMMARY OF ARGUMENT.....1

ARGUMENT 2

I. A Key Factor In This Case Is The Attorney General's Deference, And Oregon's Lack of Same, To The Medical Profession's Own Understanding of What Constitutes "Professional Practice" and "Medical Purpose." 2

II. Determining What Constitutes Professional Medical Practice and Legitimate Purpose Best Lies, In the First Instance, With The Medical Profession, Not With Individual Practitioners Or With The State. 5

III. Oregon's Assisted Suicide Policy Negatively Intrudes Upon The Professional Ethics and Ethical Practice Of Nursing. 9

CONCLUSION 14

TABLE OF AUTHORITIES

CASES:

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) 4

STATUTES:

21 U.S.C. § 801(1) 2
21 U.S.C. § 802(21) 2
Or. Rev. Stat. § 127.805(1). 1
Or. Rev. Stat. § 127.815. 3
Or. Rev. Stat. § 127.855(2). 4

OTHER AUTHORITIES:

American Nurses Association, Code of Ethics for Nurses with Interpretive Statements (2001) 10

American Nursing Association, Ethics & Human Rights Position Statements: Assisted Suicide (1994) 10

Asa Hutchinson, Administrator, Drug Enforcement Administration, Testimony before the House Comm. on Appropriations, Subcomm. On Commerce, Justice, State, and Judiciary (Dec. 11, 2001) 3

Brief of Amici Curiae Margaret P. Battin et al., Oregon v. Ashcroft, 368 F. 3d 1118 (9th Cir. 2004) (No. 0235587) 3

Carrie Farella, *Assisted Suicide: What Role for Nurses?*, NURSING SPECTRUM ONLINE (June 4, 2001) 9

Guidebook for Health Care Providers, Chap. 8 10

Oregon Nurses Association, ONA Provides Guidance on Nurses' Dilemma (1995) 12

Respondents Brief in Opposition to Petition for Writ of Certiorari filed by Peter A. Rasmussen, M.D. and David M. Hochhalter, RPh, Gonzales v. Oregon (U.S. 2005) (No. 04-623) 7

Sylvia R. Cruess et al., Analyses/Review of Literature: "Profession": A Working Definition for Medical Educators, 16 TEACHING & LEARNING IN MED. 74 (2004) 5

The Task Force to Improve the Care of Terminally-Ill Oregonians, The Oregon Death with Dignity Act: A Guidebook for Health Care Providers (2005) 9

INTEREST OF AMICUS CURIAE

The National Association of Pro-Life Nurses (NAPN) is an association of nurses with membership throughout the United States and in Oregon.[1] NAPN is dedicated to promoting respect for every human life from conception to natural death, and to affirming that the destruction of any human life, for whatever reason and by whatever means, fails to constitute good nursing practice. NAPN unites nurses who seek to excel in providing life-affirming care to all patients, including unborn and newborn children, persons with chronic disabilities, and individuals living with terminal conditions. The provision of a controlled substance "for the purpose of ending . . . life"[2] violates the ethical principles of the nursing and other medical professions. NAPN opposes any interpretation of the Controlled Substances Act that bars the Attorney General from deferring to the medical profession on the question of whether assisting suicide lies within the acceptable course of professional conduct and constitutes a legitimate medical use of controlled substances.

SUMMARY OF ARGUMENT

The Directive by the Attorney General at issue in this case defers appropriately to the widely shared and long-standing views of the medical profession. The State of Oregon's contrary policy conflicts with the medical profession's own understanding of what conduct falls within

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[1] Counsel for Petitioners and Respondents have consented to the filing of this amicus brief and their consents are filed with the Clerk of this Court. No counsel for a party authored this brief in whole or in part and the costs associated with producing and filing this brief were covered by the National Association of Pro-Life Nurses.

[2] Or. Rev. Stat. § 127.805(1).

the usual course of professional medical practice and what purposes qualify as legitimate medical goals. By prohibiting professional discipline for assisting suicides, Oregon law substitutes its own judgment for that of the medical profession. The Attorney General's deference comports with the Controlled Substances Act while Oregon's lack thereof, if incorporated into the federal law's statutory terms, turns the law on its head. Oregon's law also places medical professionals, including nurses, in an ethical bind. It forces them to abandon their professional duty to promote compliance by all members of the profession with medicine's fundamental norm of doing no harm. It also threatens nurses with undesirable degrees of involvement with suicide assistance decisions. This Court should overturn the Ninth Circuit's decision so that the Attorney General may continue to defer to the medical profession and enforce the Controlled Substances Act in a uniform manner that respects prevailing medical ethics.

ARGUMENT

I. A Key Factor In This Case Is The Attorney General's Deference, And Oregon's Lack of Same, To The Medical Profession's Own Understanding of What Constitutes "Professional Practice" and "Medical Purpose."

Congress did not define the textual references in the Controlled Substances Act (CSA) to "usual course of professional practice" or "useful and legitimate medical purpose."[3] The Attorney General defers generally to the medical profession when applying these phrases to the

[3] Controlled Substances Act, 21 U.S.C. §§ 802(21) & 801(1).

handling of federally controlled substances by federally registered medical professionals.[4]

By contrast, as the Attorney General and other amici will substantiate for this Court, the State of Oregon enforces a medical practice standard concerning patients with terminal conditions that diametrically opposes the medical profession's own consensus understanding about what constitutes the limits of professionally acceptable conduct.[5] The disparity between what Oregon authorizes and what the medical profession prohibits cannot be glossed over by referring to differences of opinion among physicians, academics and philosophers about the "ends of medicine."[6] The Attorney General is not called by the CSA to weigh and

[4] See, e.g., Asa Hutchinson, Administrator, Drug Enforcement Administration, Testimony before the House Comm. on Appropriations, Subcomm. On Commerce, Justice, State, and Judiciary (Dec. 11, 2001) ("Federal laws and regulations do not attempt to define or set standards as to what constitutes 'legitimate medical purpose' or 'the usual course of professional practice,' the requisite elements of lawful prescriptions under the CSA and DEA regulations. DEA relies upon the medical community to make these determinations.").

[5] Or. Rev. Stat. § 127.815 (authorizing physicians' assistance in the suicides of persons diagnosed as having less than six months to live).

[6] Thus, to quote from a source that disagrees with the position of your Amicus, even if "there is increasing support among medical professionals and writers in medical ethics" for medically-assisted suicide, the Attorney General must necessarily rely upon the determination of medicine's professional associations, such as the American Medical Association and the American Nurses Association, indicating that particular activities conducted by medical professionals have or have not "found a legitimate place in mainstream medical schools and wide acceptance in the everyday practice of medicine." Brief of Amici Curiae Margaret P. Battin et al. at 11, 14, Oregon v. Ashcroft, 368 F. 3d 1118 (9th Cir. 2004) (No. 0235587) (arguing that shifting understanding of the "ends of medicine" over time bolsters case for Oregon's DWDA).

contrast theoretical treatments of abstract generalities, but must determine what the medical profession itself, acting through its own professional associations and regulatory bodies, determines to be appropriate professional conduct.

Oregon's governmental interference with prevailing professional mores, accepted medical judgment, and ethics accountability is directly accomplished through the immunities section of the Oregon Death With Dignity Act (DWDA), which states in part: "No professional organization or association, or health care provider, may subject a person to censure, discipline, suspension, loss of license, loss of privileges, loss of membership or other penalty for participating . . . in good faith compliance with [the DWDA]."[7]

By enacting the DWDA, the people of Oregon have substituted their judgment as to what constitutes acceptable medical practice, overriding the plenary ethics and practice guidelines of the health care professions. Thus it is the Oregon government, not the Attorney General, that has improperly rendered, in the words of the Ninth Circuit's decision below, "a unilateral medical determination"[8] concerning the supposed legitimacy of a particular use of federally controlled substances.

The DWDA is nothing more than doctoring by popular referendum. The statute imposes on the medical profession a new and utterly foreign standard of care and disables the profession's capacity to discipline individual members participating in lethal prescriptions.

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[7] Or. Rev. Stat. § 127.855(2).

[8] Oregon v. Ashcroft, 368 F.3d 1118, 1127 (9th Cir. 2004) (Petitioner's Appendix at 17a).

If the DWDA's provisions are held to constitute the final obligatory interpretative sources for determining the meaning of "professional practice" and "medical purpose" as used in the CSA, despite their severe conflict with medicine's own understanding of these terms, then the CSA will be thrown on its head. Rather than abiding by Congress's concern about unnecessarily intruding upon medicine's professional judgments, a decision by this Court to uphold the lower court ruling will endorse the most far-reaching state interference with medicine's own determination of what is professionally acceptable with respect to the handling of controlled substances.

II. Determining What Constitutes Professional Medical Practice and Legitimate Purpose Best Lies, In the First Instance, With The Medical Profession, Not With Individual Practitioners Or With The State.

While individuals practice medicine, medicine itself is a profession that transcends individualism. "The last quarter century has seen wide agreement that a social contract exists between medicine and the society that it serves and that this contract is based on the concept of the profession."[9] Nonetheless, while the idea of social contract contemplates the involvement of society in finally determining what professionals may or may not do, the high measure of knowledge, commitment, and expertise that characterizes the professional project justifies a governmental presumption that favors the profession's own understanding over and against the general public's estimation at the ballot box of what constitutes legitimate professional conduct and purposes.

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[9] Sylvia R. Cruess et al., Analyses/Review of Literature: "Profession": A Working Definition for Medical Educators, 16 TEACHING & LEARNING IN MED. 74, 75 (2004) (emphasis added).

The term "profession" cannot be limited to either an entirely individualistic or an entirely state-defined meaning, as suggested by a recently proposed "working definition" of the term:

> Profession: An occupation whose core element is work based upon the mastery of a complex body of knowledge and skills. It is a vocation in which knowledge of some department of science or learning or the practice of an art founded upon it is used in the service of others. Its members are governed by codes of ethics and profess a commitment to competence, integrity and morality, altruism, and the promotion of the public good within their domain. These commitments form the basis of a social contract between a profession and society, which in return grants the profession a monopoly over the use of its knowledge base, the right to considerable autonomy in practice and the privilege of self-regulation. Professions and their members are accountable to those served and to society.[10]

The DWDA promotes the worst of both the individualistic and the state-driven extremes that ignore the substance and scope of the medical profession's opposition to medically-assisted suicide. For example, in a brief filed with this Court at the petition stage of this case, two medical practitioners who assist in their patients' suicides claim that they "are acting in their professional role" because such

[10] *Id.* (emphasis added).

conduct agrees with their own dissenting views and conforms to the DWDA's legal "standard of care."[11]

Yet the lethal role they have chosen to play does not respect the requisite "codes of ethics" of any of the particular healthcare professions, and the freedom they enjoy against professional sanction exists only because the DWDA bars the professions from exercising their "privilege of self-regulation" in this precise matter. Physicians assisting suicide may remain accountable to the state for failing to take various procedural steps, but they are no longer accountable to the medical profession with respect to the substantive ethical violations caused by their acts. In effect, their lethal conduct ceases to be "professional" since none of the healthcare professions authorizes it and none can penalize it.

Oregon voters altered the social contract governing medical providers by granting them the statutory license to violate the medical profession's ethical standards. The CSA, as construed by the Attorney General, maintains the traditional balance between public policy and professional prerogative by respecting medicine's ethical prohibition against suicide assistance. The DWDA employs the power of the state to release dissenting professionals from the dictates of their profession and its governing standards, and to restrain the profession from enforcing its standards for all its members.

Both the CSA, by not defining what constitutes "professional medical practice" or "medical purpose," and the Attorney General, by deferring to the medical profession to define these terms, recognize the intrinsic connection between the ethics of the medical profession and the ethical

[11] Respondents Brief in Opposition to Petition for Writ of Certiorari filed by Peter A. Rasmussen, M.D. and David M. Hochhalter, RPh at 18. Gonzales v. Oregon (U.S. 2005) (No. 04-623).

obligations of its members. This leaves the traditional social contract undisturbed and preserves for the medical profession its rightful place as the presumptive authority for determining medical ethics.

Your Amicus acknowledges that in other areas medical ethics may run counter to and at times should be subordinated to the public interest as traditionally understood, involving for example the preeminent duty to protect life. Your Amicus would support laws against abortion, therefore, to further the public interest even if the medical profession maintained policies favoring the practice and authorizing members' involvement.

The point here, however, is that the CSA directs federal enforcement agencies to consider whether particular uses of federally controlled substances are consistent with medical professional expectations and purposes. The language of the CSA, referring to "usual course of professional practice" and "useful and legitimate medical purpose" drives the Attorney General's deference to the medical profession.

As already noted, assisted suicide is deemed by the medical profession to be incompatible with the responsible conduct of its members, notwithstanding the dissenting views of individual members. The incompatibility between what the DWDA authorizes and what the ethics of the medical profession prohibits should inform this Court's decision if the goal is to implement the intent of Congress.

If the Attorney General is forced to construe the terms "professional practice" and "legitimate medical purpose" in the manner dictated by Oregon law, then federal enforcement officials will necessarily have to ignore the prevailing standards of the medical profession. They will have to allow federally registered physicians to assist in suicides in Oregon.

This will override professional duties as determined by the requisite professional associations and their regulatory bodies. Government directives will control medical ethics.

III. Oregon's Assisted Suicide Policy Negatively Intrudes Upon The Professional Ethics and Ethical Practice Of Nursing.

The DWDA permits only physicians to assist a suicide. However, other professionals, such as nurses and pharmacists are drawn inevitably into the picture. "Nurses and social workers are often the professionals with whom patients choose to talk regarding end-of-life decisions."[12] Thus, nurses in Oregon "are assuming roles they may not have anticipated, sometimes uncomfortably so. Ironically, Oregon's nurses are finding themselves, not physicians, on the front line of PAS [physician assisted suicide]."[13] As noted by one nurse: "Initially, when the law was designed, the assumption was that the physicians would be the first ones to explore PAS with patients, but in reality, nurses are usually the ones in the line of fire. Patients often feel nurses understand their wishes for good quality of life and good quality of death, too."[14]

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[12] The Task Force to Improve the Care of Terminally-Ill Oregonians, The Oregon Death with Dignity Act: A Guidebook for Health Care Providers, Chap. 8, "The Role of Other Health Care Providers" (2005) at http://www.ohsu.edu/ethics/guidebook/chapter8.pdf [hereinafter Guidebook for Health Care Providers].

[13] Carrie Farella, *Assisted Suicide: What Role for Nurses?*, NURSING SPECTRUM ONLINE (June 4, 2001) at http://community.nursingspectrum.com /MagazineArticles/article.cfm?AID=4123.

[14] *Id.* (quoting Pam Matthews, administrator for Evergreen Hospice, Albany, Oregon).

Standing at the "frontlines" because of their critical role in the daily care of patients, nurses in Oregon risk involvement with suicide decisions. A task force on implementing the DWDA convened by the Center for Ethics in Health Care at the Oregon Health Sciences University has pointed out: "The Act specifies that all health care providers shall have the right to choose whether to participate, but does not ensure them the right to know about the patient's request for life-ending medications. . . . If not informed, providers [including nurses] could become unknowing participants in physician-assisted suicide regardless of their personal views."[15]

The DWDA puts nurses in a bind. "The profession of nursing is built upon the Hippocratic tradition 'do no harm' and an ethic of moral opposition to killing another human being."[16] Further, "[i]ndividuals who become nurses are expected not only to adhere to the ideals and moral norms of the profession but also to embrace them as a part of what it means to be a nurse."[17] Thus, in their capacity as medical professionals governed by the ethical norm of "do no harm," nurses must abide by the

> primary commitment . . . to the health, well-being, and safety of the patient across the life span and in all settings in which health care needs are addressed. As an advocate for the patient, the nurse must be alert to and take

[15] Guidebook for Health Care Providers, Chap. 8.

[16] American Nursing Association, Ethics & Human Rights Position Statements: Assisted Suicide (1994) available online at http://nursingworld.org/readroom/ position/ ethics/prtetsuic.htm.

[17] American Nurses Association, Code of Ethics for Nurses with Interpretive Statements 5 (2001) available online at http://nursingworld.org /ethics/ecode.htm.

> appropriate action regarding any instances of incompetent, unethical, illegal, or impaired practice by any member of the health care team or the health care system or any action on the part of others that places the rights or best interests of the patient in jeopardy.[18]

Moreover, nursing's code of ethics recognizes that "[a]cquiescing [to] and accepting unsafe or inappropriate practices, even if the individual does not participate in the specific practice, is equivalent to condoning unsafe practice."[19] Finally, [p]rofessional autonomy and self regulation in the control of conditions of practice are necessary for implementing nursing standards and guidelines and assuring quality care for those whom nursing serves."[20]

The DWDA prevents nurses from exercising their professional duty to respond to the ethical violations of physicians and other medical professionals acting according to that law's provisions. The obligatory alertness demanded of the nurse to the occurrence of harmful behavior by other medical professionals is rendered nugatory. Conscientious nurses must stand by as the well-being and safety of terminally ill patients are threatened by legalized incidents of suicide assistance.

In short, the warping of universal professional norms caused by the DWDA distorts professional obligations and compromises the integrity of the nursing profession. The Oregon Nurses Association (ONA), in an attempt to accommodate the irreconcilable differences between the

[18] *Id.* at 14 (Interpretive Statement 3.5).

[19] *Id.* at 21 (Interpretive Statement 6.3).

[20] *Id.* at 23 (Interpretive Statement 7.2).

medical profession's foundational commitment to "do no harm" and the DWDA's endorsement of suicide assistance, cautions conscientiously opposed nurses against impeding patients seeking suicide assistance, or otherwise showing insufficient respect (in the eyes of Oregon law) for the patient's "self-determination."

This is evidenced in a position paper by the ONA,[21] which obliges nurses in Oregon to "share relevant information about health choices that are legal and to support the patient and family regardless of the decision the patient makes." This creates an expectation that nurses will have to teach patients about the option of killing themselves because assistance with such option is now legal.

Moreover,

> If the nurse becomes involved in a situation where he/she is unwilling to be involved in the care of a patient who has chosen assisted suicide, the nurse continues to be obliged to provide for the patient's comfort and safety, and to withdraw only when assured that alternative sources of end of life care are available to the patient. If the nurse is unable to transfer care to another provider, the nurse has the responsibility to provide for ongoing end of life care.[22]

In other words, nurses opposed to assisted suicide may be forced by emergent circumstances to accommodate

[21] Oregon Nurses Association, ONA Provides Guidance on Nurses' Dilemma (1995), available online at http://www.oregonrn.org/services-whitepapers-0001.php.

[22] *Id.*

patients under their care who want to commit suicide pursuant to the DWDA. Requesting and securing a replacement nurse from an agency (if even granted) could take too long or not be possible. Thus, nurses seeking to abide by their professional obligations not only are barred from initiating any protective measures consistent with professional norms, but may themselves be forced as a practical matter to acquiesce in ways contradicting those norms.

All this serves to undermine the uniform and fundamental value system that inspires nurses and other medical professionals across the country to enter the profession. It weakens the normative force of these values, values that otherwise guide the professional care of the terminally ill in every other state but Oregon. A decision by this Court requiring Oregon's revised interpretation of "professional" obligations to be incorporated into the CSA's reference to "professional practice" will abet the ultimate dissolution of medicine's professional integrity. The CSA, if interpreted by reference to Oregon law, will become the tool by which state interference with medical judgment will diminish the authority and capacity of medicine to sustain its foundational principles.

It all comes back to the essential difference discussed at the beginning of this brief. The Attorney General seeks to defer to a prevailing medical standard that values the lives of the terminally ill while Oregon overrides it.

Adopting Oregon's interpretation of the CSA will thwart the will of Congress, cause excessive state interference with the professional standards of medicine, put nurses and other medical professionals in an ethical bind, and expose the terminally ill to a dangerous double standard that recognizes the inalienable right to life of the healthy but not of the dying.

CONCLUSION

In light of this, your Amicus urges this Court to reverse the Ninth Circuit's decision and uphold the Attorney General's Directive barring federal registrants from prescribing federally controlled substances for the purpose of assisting suicide.

Respectfully submitted,

DANIEL AVILA, ESQ.
31 Linden Street
Everett, MA 02149
(617) 387-3049

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No. 04-623

IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

STATE OF OREGON, ET AL.,

Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

AMICUS BRIEF OF AMERICAN CENTER FOR LAW AND JUSTICE IN SUPPORT OF PETITIONERS

THOMAS P. MONAGHAN
CHARLES E. RICE
CENTER FOR LAW & JUSTICE INTERNATIONAL
6375 New Hope Road
New Hope, KY 40052
(502) 549-5454

JAY ALAN SEKULOW
Counsel of Record
COLBY M. MAY
JAMES M. HENDERSON, SR.
WALTER M. WEBER
AMERICAN CENTER FOR LAW & JUSTICE
201 Maryland Avenue, N.E.
Washington, DC 20002
(202) 546-8890

Attorneys for Amicus Curiae

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF AMICUS 1

SUMMARY OF THE ARGUMENT 1

ARGUMENT 2

I. Oregon Lacks Standing to Bring this Suit. 2

A. Background 3

B. Oregon's Lack of Standing 3

II. Oregon's Attack on the Constitutional Basis for the CSA Cannot Serve as an Alternate Grounds for Affirming the Judgment. 6

A. Pertinence of Commerce Clause Issue 6

B. Validity of CSA and Ashcroft Directive Under Commerce Clause 7

CONCLUSION 10

TABLE OF AUTHORITIES

Page

CASES

Alfred L. Snapp & Son v. Puerto Rico ex rel. Barez, 458 U.S. 592 (1982) 5

Bowen v. Public Agencies Opposed to Social Security, 477 U.S. 41 (1986) 6

Diamond v. Charles, 476 U.S. 54 (1985) 3

Maine v. Taylor, 477 U.S. 131 (1986) 5

Massachusetts v. Mellon, 262 U.S. 447 (1923) 1, 4, 5, 6

Minor v. United States, 396 U.S. 87 (1969) 9

Oregon v. Ashcroft, 192 F. Supp. 2d 1077 (D. Ore. 2002) 3, 5

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) 3, 7

Perez v. United States, 402 U.S. 146 (1971) 2, 8

Reina v. United States, 364 U.S. 507 (1960) 10

Solid Waste Agency of Northern Cook County v. Army Corps of Engineers, 531 U.S. 159 (2001) 7

South Carolina v. Katzenbach, 383 U.S. 301 (1966) 5

United States v. Darby, 312 U.S. 100 (1941) 8

United States v. Lopez, 514 U.S. 549 (1995) 7

CONSTITUTIONAL PROVISIONS AND STATUTES

U.S. Const. art. I, § 8, cl. 3 ..... 2, 6, 7, 9, 10

U.S. Const. art. III 1, 3, 4, 6

18 U.S.C. § 1951 7

INTEREST OF AMICUS[1]

The American Center for Law and Justice (ACLJ) is a public interest law firm,[2] international in scope, committed to insuring the ongoing viability of constitutional freedoms in accordance with principles of justice. The Chief Counsel for the ACLJ has presented oral argument eleven times before the Supreme Court of the United States. ACLJ attorneys have participated as counsel of record for parties and for amici curiae in numerous cases before state and federal appellate courts, including this Court.

The ACLJ supports the U.S. Department of Justice in its efforts to bar the use of federally controlled substances to perpetrate intentional acts of assisted suicide. The ACLJ likewise opposes the Ninth Circuit's holding that the federal government must surrender the uniform enforcement of drug laws to the misguided, suicide-endorsing laws of a particular state.

SUMMARY OF THE ARGUMENT

1. The respondent state of Oregon lacks standing to challenge the Ashcroft Directive. Under *Massachusetts v. Mellon*, 262 U.S. 447 (1923), it is insufficient under Article III for a state baldly to assert that federal action usurps local powers reserved to the states.

Mellon likewise bars a state from suing the federal

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[1]The parties in this case have consented to the filing of this brief. Copies of the consent letters are being filed herewith. No counsel for any party authored this brief in whole or in part. No person or entity aside from the ACLJ, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

[2]The ACLJ has no parent corporation, and no publicly held company owns 10% or more of its stock.

government by invoking *parens patriae* standing on behalf of its citizens. Hence, should this Court reverse the Ninth Circuit on the merits, it should also hold that Oregon lacks standing to participate in further proceedings on remand.

2. Oregon claimed below that Congress lacks power under the Commerce Clause to regulate the activities governed by the Ashcroft Directive, and so the federal Controlled Substances Act (CSA) is unconstitutional, to the extent that it authorized Attorney General Ashcroft to issue that directive. Before this Court, Oregon contends that concern over these same Commerce Clause limitations justifies a narrow construction of the CSA, one that would render the Ashcroft Directive statutorily unauthorized. Oregon's Commerce Clause argument, however, is wholly meritless. The CSA lawfully regulates controlled substances *as a class*, and therefore the intrastate nature of particular instances of conduct is irrelevant. *Perez v. United States*, 402 U.S. 146 (1971). Oregon's attempt to raise an "as applied" Commerce Clause challenge must therefore fail. Oregon blurs the distinction between federal regulation of specific acts of conduct with an interstate nexus (as with the Hobbs Act) and federal regulation of a class of acts that Congress has found categorically to be within or to affect interstate commerce (as with the CSA). To the extent Oregon's claim is simply a facial challenge to the CSA, it fails under this Court's precedents.

This Court should reverse the judgment of the Ninth Circuit.

ARGUMENT

I. Oregon Lacks Standing to Bring this Suit.

The state of Oregon, a respondent here, lacks standing in this case. This matter is significant because, should the petitioners prevail in this Court, the case will be remanded for further proceedings.

A. Background

Three distinct sets of parties challenged the Ashcroft directive in district court: Oregon (plaintiff below); medical practitioners (intervenors below); and patients (intervenors below). All are respondents in this Court.

Petitioners early on moved to dismiss Oregon from the case for lack of standing. *See Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1087 (D. Ore. 2002). The district court denied this motion. Viewing the Attorney General's directive as an intrusion on Oregon's "sovereign and legitimate interest in the continued enforceability of its own statutes," the district court ruled that Oregon has standing to challenge that directive. *Id.*

The Ninth Circuit did not endorse that holding. Instead, the court held only that the respondent health care practitioners have standing. *Oregon v. Ashcroft*, 368 F.3d 1118, 1121 (9th Cir. 2004). The court of appeals did *not* decide whether the other plaintiffs -- including respondent Oregon -- also have standing. *Id.* at 1121 n.2.[3] Tellingly, while the Ninth Circuit suggested that the respondent *patients* might also have standing, *id.*, the court made no effort to endorse *Oregon*'s claim of standing, *id.*

B. Oregon's Lack of Standing

The Attorney General's directive does not infringe upon any

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[3]The Ninth Circuit invalidated the Ashcroft directive. Given this ultimate holding of invalidity -- which, if left intact, would effectively end the litigation -- it was unnecessary for the Ninth Circuit to decide the standing of the other challengers. Should this Court reverse the Ninth Circuit's judgment on the merits, there will be additional proceedings on remand. In such a case, whether Oregon enjoys party status will indeed be a matter of consequence. The remaining respondents would presumably still be able to challenge the Ashcroft Directive as intervenors, assuming that they in fact have Article III standing. *Diamond v. Charles*, 476 U.S. 54, 68 (1985). But Oregon itself could no longer litigate this case.

sovereign interest of Oregon. The Attorney General's actions raise no question concerning either the constitutionality or the enforceability of Oregon's assisted suicide statute, the so-called Death With Dignity Act (DWDA). The DWDA itself is not even at issue; only the availability of certain means, *i.e.*, using federally controlled substances, to accomplish the suicides authorized by the DWDA, is at stake. Indeed, Oregon concedes as much. *See* Brief for Respondent State of Oregon in Opposition ("Ore. Opp.") at 9 n.7 ("petitioner [Attorney General] does not suggest that the DWDA is invalid. He asserts only that his authority over controlled substances allows him to prevent their use for purposes authorized by the Oregon law"); *id.* at 10 ("At most, this case is about the means those physicians can use"); Reply Brief for the Petitioners at 5 (concurring with Oregon's concession).

Under these circumstances, Oregon plainly lacks Article III standing. *Massachusetts v. Mellon*, 262 U.S. 447, 480-86 (1923). As in *Mellon*, Oregon "complains that the act in question invades the local concerns of the State, and is a usurpation of power, viz.: the power of local self government reserved to the States." *Id.* at 480. But as in *Mellon*, "the powers of the State are *not* invaded," *id.* (emphasis added). Oregon's DWDA remains valid, and the Ashcroft Directive imposes no new obligation whatsoever upon the state. All the directive does is to narrow the range of *means* legally available to commit suicide under the DWDA.

> What, then, is the nature of the right the State here asserted and how is it affected by this [directive]? Reduced to its simplest terms, it is alleged that the [directive] constitutes an attempt to [regulate] outside the powers granted [by] Congress and [by] the Constitution and within the field of local powers exclusively [or presumptively] reserved to the States. . . . But what burden is imposed upon the States . . . ? Certainly

> there is none, unless it be the burden [which] falls upon their inhabitants . . . . Nor does the [directive] require the States to do or to yield anything.

Id. at 482.

The only injury, if there is any, occasioned by the Attorney General's directive is to those who desire to use or administer Schedule II substances contrary to federal drug law. Thus, at best, Oregon's interest may be characterized as a *parens patriae* interest on behalf of those persons. On this theory, as well, *Mellon* is dispositive:

> It cannot be conceded that a State, as *parens patriae*, may institute judicial proceedings to protect citizens of the United States from the operation of the statutes thereof. While the State, under some circumstances, may sue in that capacity for the protection of its citizens . . . it is no part of its duty or power to enforce their rights in respect of their relations with the Federal Government. In that field it is the United States, and not the State, which represents them as *parens patriae*, when such representation becomes appropriate; and to the former, and not to the latter, they must look for such protective measures as flow from that status.

Id. at 485-86 (citation omitted). *Accord South Carolina v. Katzenbach*, 383 U.S. 301, 323-24 (1966); *Alfred L. Snapp & Son v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982).[4]

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[4]The district court relied upon two of this Court's cases for its holding that Oregon has standing. *See* 192 F. Supp. 2d at 1087. Neither is applicable here.

The first case, *Maine v. Taylor*, 477 U.S. 131 (1986), involved the constitutionality of a Maine statute; this Court held that Maine had standing to intervene to defend its own law. 477 U.S. at 133, 137. Here, by contrast,

(continued...)

If Oregon were deemed to have standing in this case, then a vast number of federal statutes or agency actions would be subject to challenge *by states*. Countless federal restrictions forbid private parties from engaging in conduct that would otherwise be permissible under state law. For example, federal laws governing drug labeling, food packaging, the environment, securities transactions, and labor relations all impose requirements beyond what is required under state law. Plainly, private citizens affected by such restrictions can challenge them. But the lesson of *Mellon* is that a state cannot do so, either on its own behalf or on behalf of its citizens, under the theory that the federal government has disrupted its sovereignty. If such federal regulations were deemed interference with "a state's sovereign interest in enforcing its laws" cognizable under Article III, then state attorneys general would be free to bring suit against any and all federal laws, regulations, or executive actions that impose additional requirements beyond those set by state law. If so, then *a fortiori* a state could sue whenever a federal statute preempted any state law.

This is not what Article III permits. Oregon lacks standing.

II. Oregon's Attack on the Constitutional Basis for the CSA Cannot Serve as an Alternate Grounds for Affirming the Judgment.

A. Pertinence of Commerce Clause Issue

In the proceedings below, Oregon claimed that the Commerce Clause does not empower Congress to regulate controlled

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[4](...continued)
the constitutionality of Oregon's DWDA is not at issue. In the second case, *Bowen v. Public Agencies Opposed to Social Security*, 477 U.S. 41 (1986), a federal statute forbade states from withdrawing state employees from the Social Security system, *id.* at 48. Here, there is no federal interference with state employment contracts, or any federal compulsion of states at all.

substances in the case of prescriptions for suicide. *See, e.g.*, Appellee's Brief of the State of Oregon at 63-69; Ore. Opp. at 5 n.6. The Ninth Circuit did not reach this argument. *See* 368 F.3d at 1125. Oregon did not renew this argument in its Brief in Opposition. *See* Ore. Opp. at 10 ("only questions" presented are statutory interpretation issues).

Oregon nevertheless continues to argue, in support of a narrow construction of the federal Controlled Substances Act (CSA), that the CSA "pushes the boundaries of Congressional power," Ore. Opp. at 17 (citing *Solid Waste Agency of Northern Cook County v. Army Corps of Engineers*, 531 U.S. 159 (2001), a case that invoked Commerce Clause concerns in support of a narrow statutory construction). Thus, the Commerce Clause issue still lurks in the backdrop of this case. It is therefore worthwhile to demonstrate how truly meritless Oregon's Commerce Clause challenge is.

B. Validity of CSA and Ashcroft Directive Under Commerce Clause

While Oregon may seek to portray this case as raising a modest "as applied" challenge, it is no such thing. To embrace Oregon's argument would be to strike the CSA on its face, throughout the nation.

Federal legislation under the Commerce Clause falls into two broad categories. First, statutes can regulate activities on a case-by-case basis, with proof of a connection to interstate commerce necessary for any particular application. *E.g.*, 18 U.S.C. § 1951 (federal robbery and extortion statute; contains element of "affect[ing] commerce or the movement of any article or commodity in commerce"). *See generally United States v. Lopez*, 514 U.S. 549, 561-62 (1995). Second, statutes can address a class of economic activities, such as pricing milk or producing wheat, without any need to prove a nexus to interstate

commerce in particular cases. *E.g.*, *Perez v. United States*, 402 U.S. 146 (1971) (extortionate credit transactions). *See generally id.* at 150-52.

The CSA falls into the second category. It regulates the dispensing of controlled substances *as a class*, regardless of any nexus to interstate commerce in individual situations. If the CSA is valid generally, then it cannot be struck down on the ground that, "as applied" in the case of prescribed suicides in Oregon, Congress exceeded its constitutional power. As this Court has explained: "Where the *class of activities* is regulated and that *class* is within the reach of federal power, the courts have no power to excise, as trivial, individual instances of the class." *Perez*, 402 U.S. at 154 (emphasis in original; internal quotation marks and citation omitted).

Oregon therefore has it exactly wrong when it claims that the Ashcroft Directive is unconstitutional because "[t]he effect of the conduct regulated under Ashcroft's interpretation of the CSA is nothing if not 'trivial.'" Appellee's Brief of the State of Oregon at 67. This Court's decision in *Perez* directly forecloses that argument.

What is more, Oregon's argument makes little sense as a matter of constitutional policy. Under Oregon's theory, Congress could not regulate any activity *as a category*. Congress (or, perhaps, the Executive in an enforcement action), instead, would be required to prove that each and every good, service, or activity sought to be regulated federally itself satisfied this novel constitutional jurisdictional requirement. Oregon thus would obliterate the longstanding distinction between federal statutes that have specific jurisdictional proof requirements (*e.g.*, a firearm that has moved in interstate commerce) and federal statutes that do not (*e.g.*, extortionate credit transactions), *see, e.g.*, *Perez*, 402 U.S. at 152 (quoting *United States v. Darby*, 312 U.S. 100, 120-21 (1941)), because none of the latter would be

constitutional.

The limitation that this theory would impose on federal regulatory power is breathtaking. Consider just the universe of controlled substances: Under Oregon's view, Congress could not regulate a controlled substance -- take methamphetamine as an example -- that was manufactured, distributed, and used entirely intrastate, because there would be no proof of an interstate nexus. It is no understatement to say that this theory would hobble, if not cripple, federal narcotics enforcement efforts in the case of, perhaps, most controlled substances, certainly any controlled substance that could be grown or manufactured in this country. Given the nation's commitment to protect the public against the manifold dangers caused by the use of and trafficking in controlled substances, Oregon's theory has little to commend it -- except as a means of reducing the number of federal inmates.

In short, for Oregon to prevail on its Commerce Clause argument, the CSA would have to be invalid on its face, which would strike the statute down in all its applications, across the nation. This conclusion follows logically from the nature of Oregon's challenge. The power of Congress under the Commerce Clause does not hinge on the lawfulness of the activity in question under state law. Therefore, if it exceeds the power of Congress to regulate the prescription of drugs for suicide in Oregon where that activity is lawful, then it similarly exceeds the power of Congress in all 49 other states where that practice is unlawful.[5] But federal control of narcotics is constitutionally valid under the Commerce Clause, as this Court as long held. *See Minor v. United States*, 396 U.S. 87, 98 n.13

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[5]Likewise, if the prescription of drugs for suicide is beyond federal legislative reach because it is supposedly wholly unrelated to drug trafficking, then so is the prescription of drugs for legitimate medical purposes, which is arguably just as unrelated to illegal trafficking.

(1969); *Reina v. United States*, 364 U.S. 507, 511 (1960) (and cases cited). Hence, Oregon's Commerce Clause challenge must be rejected. For the same reason, there is no need here for recourse to the doctrine of constitutional avoidance.

CONCLUSION

This Court should reverse the judgment of the Ninth Circuit.

Respectfully submitted,

Thomas P. Monaghan
Charles E. Rice
Center for Law and Justice International
6375 New Hope Road
New Hope, KY 40052
(502) 549-5454

Jay Alan Sekulow
Counsel of Record
Colby M. May
James M. Henderson, Sr.
Walter M. Weber
American Center for Law and Justice
201 Maryland Ave., NE
Washington, DC 20002
(202) 546-8890

Attorneys for Amicus Curiae

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IN THE

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PETITIONERS,

v.

STATE OF OREGON, *et al.*
RESPONDENTS.

On Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* NOT DEAD YET, ADAPT, CENTER ON DISABILITY STUDIES, LAW AND POLICY AT SYRACUSE UNIVERSITY, CENTER FOR SELF-DETERMINATION, HOSPICE PATIENTS ALLIANCE, MOUTH MAGAZINE/FREEDOM CLEARINGHOUSE, NATIONAL COUNCIL ON INDEPENDENT LIVING, NATIONAL SPINAL CORD INJURY ASSOCIATION, SELF-ADVOCATES BECOMING EMPOWERED, SOCIETY FOR DISABILITY STUDIES, TASH AND THE WORLD INSTITUTE ON DISABILITY IN SUPPORT OF PETITIONERS

Max Lapertosa
Counsel of Record
Kenneth M. Walden
Adrienne Detanico, Law Clerk
ACCESS LIVING
614 West Roosevelt Road
Chicago, IL 60630

Walter J. Kendall III
Professor of Law
THE JOHN MARSHALL LAW SCHOOL
315 South Plymouth Court
Chicago, IL 60604

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF AMICI CURIAE 1

A. Not Dead Yet 3

B. ADAPT 3

C. Center on Disability Studies, Law and Human Policy at Syracuse University 4

D. Center for Self-Determination 4

E. Hospice Patients Alliance 4

F. Mouth Magazine/Freedom Clearinghouse 5

G. National Council on Independent Living 5

H. National Spinal Cord Injury Association 5

I. Society for Disability Studies.. 6

J. Self-Advocates Becoming Empowered 6

K. TASH 6

L. World Institute on Disability 6

SUMMARY OF ARGUMENT 7

ARGUMENT 8

I. Assisted Suicide Serves No Legitimate Medical Purpose Because It Discriminates Against and Degrades the Lives of People with Disabilities 8

A. Laws, Programs and Services Operate to Prevent People from Committing Suicide 8

B. The Oregon Assisted Suicide Law Denies People with Disabilities the Benefits of Suicide Prevention Laws and Measures 10

C. Euthanasia and Assisted Suicide Are Part of the Long and Tragic History of Discrimination Against People with Disabilities 11

D. Assisted Suicide Contravenes Medical Ethics and Practice Because of the Abuse It Poses to People with Disabilities 14

1. The Uncertainty of Diagnosing a "Terminal Illness" 14

2. The Law's False Assumption that Suicide is "Rational" When Committed By a Person with a Disability 16

3. The Law's False Assumption that Disability Intrinsically Deprives Life of Dignity and Value 18

4. The Difficulty in Ensuring Decisions to Die Are Not Coerced or Made by Others 22

II. The Attorney General's Determination that Assisted Suicide is Not a "Legitimate Medical Practice" is a Permissible Construction of the Controlled Substances Act 23

A. The Attorney General's Interpretive Ruling is Entitled to Deference 23

B. The "Clear Statement" Rule Does Not Apply to Regulation of the Practice of Medicine 25

CONCLUSION 28

TABLE OF AUTHORITIES

CASES

Abbott v. Bragdon, 912 F. Supp. 580 (D. Me. 1995), *aff'd*, 107 F.3d 934 (1st Cir. 1997), *vacated & remanded*, 524 U.S. 624 (1998) 28
ADAPT v. Philadelphia Hous. Auth., 2000 U.S. Dist. LEXIS 5380 (E.D. Pa. Apr. 14, 2000) 3
ADAPT v. Skinner, 881 F.2d 1184 (3d Cir. 1989) 3
ADAPT v. SkyWest Airlines, 762 F. Supp. 320 (D. Ut. 1991) 3
Atascadero State Hosp. v. Scanlon, 473 U.S. 234 (1985) ... 27
Barnhart v. Walton, 535 U.S. 212 (2002) 24, 25
Bragdon v. Abbott, 524 U.S. 624 (1998) 24, 27-28
Buck v. Bell, 274 U.S. 200 (1927) 12
Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1982) 7, 23-25
City of Cleburne v. Cleburne Living Center, 473 U.S. 432 (1985). 12, 26
Equal Employment Opportunity Comm'n v. Massachusetts, 987 F.2d 64 (1st Cir. 1993) 26
Gregory v. Ashcroft, 501 U.S. 452 (1991) 7-8, 25-26
Helen L. v. DiDario, 46 F.3d 325 (3d Cir.), *cert. denied sub nom., Secretary of Publ. Welf. v. Idell S.*, 516 U.S. 813 (1995) 3
In re Grand Jury Proceedings, 801 F.2d 1164 (9th Cir. 1986) 26
In re Kober's Will, 285 P. 1032 (Or. 1930) 9
In re Simpson, 180 N.E. 2d 206 (Ct. Common Pleas Oh. 1962) 12
McKay v. Bergstedt, 801 P.2d 617 (Nev. 1990) 21-22
Minor v. United States, 396 U.S. 87 (1969) 26
Olmstead v. L.C., 527 U.S. 581 (1999) 20, 24, 27
Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004). 25-26
Reina v. United States, 364 U.S. 507 (1960) 26

School Comm. of Burlington v. Massachusetts Dep't of Educ., 471 U.S. 359 (1985). 12
Solid Waste Agency v. Army Corps of Engineers, 531 U.S. 159 (2001) 25
Tennessee v. Lane, 541 U.S. 509, 124 S. Ct. 1978 (2004) 26
United States v. Moore, 423 U.S. 122 (1975) 24, 27
Vacco v. Quill, 521 U.S. 793 (1997) 14
Washington v. Glucksberg, 521 U.S. 702 (1997) 2, 3, 8, 11, 14, 16
Wyckoff v. Mutual Life Ins. Co., 147 P.2d 227 (Or. 1944) 9

FEDERAL STATUTES

Americans with Disabilities Act,
42 U.S.C. §§ 12101-12181 1
42 U.S.C. § 12132 10
Controlled Substances Act, 21 U.S.C. §§ 801-971 ..... 7, 24
21 U.S.C. § 801(2). 24
21 U.S.C. § 822(b) 24
21 U.S.C. § 823(f). 24
21 U.S.C. § 871(a). 24
Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-397 27
Section 504 of the Rehabilitation Act,
29 U.S.C. § 794(a). 10

STATE STATUTES

Alaska Stat. §§ 44.29.300-44.29.390 9
Ariz. Rev. Stat. § 13-403 8
Ariz. Rev. Stat. § 36.3415 9
Ark. Code Ann. § 6-18-1005 9
Cal. Gov. Code § 53110 9
Cal.Welf. & Inst. Code §§ 4098 – 4098.5 9
Conn. Gen. Stat. § 7-294g 9
Del. Code Ann. tit. 11, § 467 8
9 Guam Code Ann. § 7.92 8

Haw. Rev. Stat. § 703.308 8
410 Ill. Comp. Stat. 53/5-15 9
La. Rev. Stat. Ann. § 17.282.4 9
Mass. Ann. Laws ch. 40, § 36C 9
Md. Code Ann., Health-General § 10-1403(a)(1)(iii) 9
Minn. Stat. § 146.56 9
Mo. Rev. Stat. § 630.900 9
N.D. Cent. Code § 12.1-05 8
N.D. Cent. Code § 57-40.6-10 9
N.H. Rev. Stat. § 186.67-a 9
N.H. Rev. Stat. Ann. § 627.6 8
N.J. Stat. Ann. § 2C:3-7 8
N.J. Stat. Ann. §§ 30:9A-13 – 30:9A-27 9
Neb. Rev. Stat. § 28.1412 8
Nev. Rev. Stat. §§ 439.511 – 439.513 9
Okla. Stat. Ann. §§ 12-101 – 12-105 9
The Oregon "Death with Dignity" Act,
Or. Rev. Stat. §§ 127.800 – 127.995 ..... 1, 10
Or. Rev. Stat. § 127.825 17
Or. Rev. Stat. § 161.205(4) 8
Or. Rev. Stat. § 163.125 8
Or. Rev. Stat. § 181.860(8)(a) 9
Or. Rev. Stat. § 418.748 9
Or. Rev. Stat. § 418.756 9
Or. Rev. Stat. § 441.750 9
Or. Rev. Stat. § 656.310 9
18 Pa. Cons. Stat. § 508 8
24 P.R. Laws Ann. §§ 3241 – 3244 9
R.I. Gen. Laws § 16-22-14 9
Tenn. Code Ann. § 39-11-613 8
Va. Code Ann. § 32.1-73.7 9
Wis. Stat. § 939.48 8

FEDERAL REGULATIONS

21 C.F.R. § 1306.04(a). 7, 24

OTHER AUTHORITIES

American Medical Association,
Code of Ethics § 2.211 2
Evelyn Hoover Barnett,
Is Mom Capable of Choosing to Die?
The Oregonian, Oct. 16, 1999, at G1 ..... 2, 22
William Breitbart *et al.*,
Depression, Hopelessness and Desire for Hastened Death in Terminally Ill Patients with Cancer,
284 JAMA 2907 (Dec. 13, 2000). 16, 18
Harvey Max Chochinov *et al.*,
Dignity in the Terminally Ill: A Cross-Sectional, Cohort Study,
360 The Lancet 2026 (Dec. 28, 2002) 20
Kathleen M. Foley,
Competent Care for the Dying Instead of Physician-Assisted Suicide,
336 New Eng. J. Med. 54 (Jan. 2, 1997) 19
Linda Ganzini *et al.*,
Evaluation of Competence to Consent to Assisted Suicide: Views of Forensic Psychiatrists,
157 Am. J. Psychiatry 595 (Apr. 2000) 17, 21
Carol J. Gill, *Suicidal Intervention for People with Disabilities: A Lesson in Inequality*,
8 Issues in L. & Med. 37 (1992) 11
Herbert Hendin *et al.*,
Physician-Assisted Suicide: The Dangers of Legalization,
150 Am. J. Psychiatry 14 (Jan. 1993). 16, 18
Herbert Hendin,
Seduced by Death: Doctors, Patients and the Dutch Cure (1997) 2
Herbert Hendin,
Seduced by Death: Doctors, Patients and the Dutch Cure,
10 Issues in L. & Med. 123 (1994). 15

Stanley S. Herr,
No Place to Go: Refusal of Life-Sustaining Treatment by Competent Persons with Physical Disabilities,
8 Issues in L. & Med. 3 (1992) 21
Brendan D. Kelly et al.,
Euthanasia, Assisted Suicide and Psychiatry: A Pandora's Box,
181 British J. Psychiatry 278, 279 (2002) 17, 18
Evan J. Kemp, *Could You Please Die Now?*
Wash. Post, Jan. 5, 1997, at C1 16
H. Laughlin,
Eugenic Sterilization in the United States (1922) 12
James V. Lavery *et al.*,
Origins of the Desire for Euthanasia and Assisted Suicide in People with HIV-1 or AIDS: A Qualitative Study,
358 The Lancet 362 (Aug. 4, 2001) 19, 21
Robert J. Lifton,
The Nazi Doctors: Medical Killing and the Psychology of Genocide (1986) 13
National Council on Disability,
Assisted Suicide: A Disability Perspective
(1997, re-released 2005). 2, 15, 18
M. Louis Offen, *Dealing with "Defectives": Foster Kennedy and William Lenox on Eugenics*,
61 Neurology 668 (Sept. 2003) 13
Oregon Department of Human Services,
Oregon's Death with Dignity Act: Three Years of Physician-Assisted Suicide (2001) 19-20
Oregon Department of Human Services,
Seventh Annual Report on Oregon's Death with Dignity Act (2005) 15, 17
Timothy E. Quill *et al.*,
Sounding Board: Care of the Hopelessly Ill,
327 New Eng. J. Med. 1380 (Nov. 5, 1992) 14

Lori A. Roscoe *et al.*,
Dr. Jack Kevorkian and Cases of Euthanasia in Oakland County, Michigan, 1990-1998,
343 New Eng. J. Med. 1735 (Dec. 7, 2000) 2, 15
Peter Singer,
Rethinking Life and Death: The Collapse of Our Traditional Ethics (1994) 13
The Right to Kill, Time, Nov. 18, 1935, at 53-54 13
The Surgeon General's Call to Action to Prevent Suicide 1999 ..... 1, 8
Peter Van der Maas *et al.*,
Euthanasia and Other Medical Decisions Concerning the End of Life,
338 The Lancet 669 (1991) 15, 18, 22
World Health Organization,
World Report on Violence and Health (2002) 9

INTEREST OF AMICI CURIAE

Amici are among the nation's leading organizations representing people with disabilities. Most are governed and staffed by a majority of people with disabilities of all types. They played a key role in enacting the nation's civil rights laws for people with disabilities, including the Americans with Disabilities Act, 42 U.S.C. §§ 12101-12181. Based on their shared experience as people with disabilities, including conditions judged to be "terminal," *Amici* strongly oppose the legalization of assisted suicide.[1]

In the United States, as in most other nations, a person who attempts or desires to commit suicide will typically be rushed to the nearest emergency room, as one-half million Americans are each year. *The Surgeon General's Call to Action to Prevent Suicide 1999* 1. The person will be subject to numerous laws, programs, and medical and therapeutic interventions designed to convince him or her not to commit suicide, or to prevent him or her from doing so. *Id.*

It seems axiomatic that society's response to a person who attempts suicide should not differ based on that person's race, ethnicity, gender, religion or disability. Yet Oregon's "Death with Dignity" Act, Or. Rev. Stat. §§ 127.800 – 127.995, encourages, rather than discourages, certain people to die solely because of their disability. Indeed, the law *guarantees* that the suicide attempts of the severely disabled will succeed. Although the Surgeon General has stated that suicide prevention policies "must recognize and affirm the value, dignity and importance of each person," *Surgeon General's Call to Action* at 13, Oregon's assisted suicide law implicitly states that some people's lives are worth saving

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[1] The parties have consented to the filing of this brief. No counsel for a party has authored this brief, in whole or in part, and no person other than *amici* and their counsel has made any monetary contribution for its preparation.

and others are not. For *amici*, this debate is not about the "choice" of someone who is suicidal. Rather, it is about demanding a uniform legal and societal response to those who want to kill themselves. *Amici*'s experience as people with disabilities is that the false assumption that suicide is a rational solution to the barriers and discrimination they face devalues them as human beings and sanctions their unequal treatment under law.

Supporters of physician-assisted suicide laws such as Oregon's claim they are limited only to competent people who face imminent death as a result of terminal illness. Yet neither Oregon's system of physician-assisted suicide nor any other – whether *de jure* (the Netherlands)[2] or *de facto* (Dr. Kevorkian)[3] – has operated within these boundaries. Physician-assisted suicide invites anyone involved in the decision to die, including the physician, to make monumental judgments on the relative value of a person's life – or, as one Oregon reporter noted, to act as "the gatekeepers of death." Evelyn Hoover Barnett, *Is Mom Capable of Choosing to Die?* The Oregonian, Oct. 16, 1999, at G1. It is no coincidence, then, that this Court has refused to recognize assisted suicide as a fundamental right, *see Washington v. Glucksberg*, 521 U.S. 702, 735 (1997), the medical profession has eschewed it as a legitimate practice, *see* American Medical Association, Code of Ethics § 2.211, and every other state besides Oregon has refused to allow it shelter under their laws, *Glucksberg*, 521 U.S. at 710. And, as *Amici* here submit, it is condemned by the vast majority of people with disabilities. *See* National Council on Disability, *Assisted Suicide: A Disability Perspective* (1997, re-released 2005).

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[2] *See* Herbert Hendin, *Seduced by Death: Doctors, Patients and the Dutch Cure* (1997), cited in *Washington v. Glucksberg*, 521 U.S. 702, 730 (1997).

[3] *See* Lori A. Roscoe *et al.*, *Dr. Jack Kevorkian and Cases of Euthanasia in Oakland County, Michigan, 1990-1998*, 343 New Eng. J. Med. 1735 (Dec. 7, 2000).

A. Not Dead Yet

Not Dead Yet is a national grassroots organization of people with disabilities formed in response to the movement to permit physician-assisted suicide and euthanasia in the United States and around the world. Not Dead Yet's mission is to protect the civil rights of people with disabilities by advocating against discriminatory legalization of physician-assisted suicide and euthanasia and to bring a disability-rights perspective and awareness of the effects of discrimination to the legal and sociological debate surrounding these practices. Not Dead Yet has worked to educate, support, coordinate and lead the disability community's effort to stop the "right to die" from becoming a duty to die or a right to kill. This Court cited Not Dead Yet's *amicus* brief in *Washington v. Glucksberg*, 521 U.S. 702, 733 n.23 (1997). Not Dead Yet has also testified before the U.S. Congress three times on the subject of physician-assisted suicide.

B. ADAPT

ADAPT is a national disability rights organization comprised primarily of people with disabilities. ADAPT has a long history and record of enforcing the civil rights of people with disabilities. In addition to being one of the key organizations that helped enact the Americans with Disabilities Act, ADAPT has been a plaintiff in numerous civil rights lawsuits. *See e.g. ADAPT v. Skinner*, 881 F.2d 1184 (3d Cir. 1989); *Helen L. v. DiDario*, 46 F.3d 325 (3d Cir.), *cert. denied sub nom., Secretary of Publ. Welf. v. Idell S.*, 516 U.S. 813 (1995); *ADAPT v. Philadelphia Hous. Auth.*, 2000 U.S. Dist. LEXIS 5380 (E.D. Pa. Apr. 14, 2000); *ADAPT v. SkyWest Airlines*, 762 F. Supp. 320 (D. Ut. 1991).

C. Center on Disability Studies, Law and Human Policy at Syracuse University

The Center on Disability Studies, Law and Human Policy is an interdisciplinary disability research and policy institute at Syracuse University. Established in 1971, the Center's work focuses on people with cognitive disabilities. The Center's research has included studies of institutions, schools, and community services, the history of the treatment of people with disabilities in America, disability law and policy, images of disability in the media and popular culture, and the politics and ethics of treatment.

D. Center for Self-Determination

The Center for Self-Determination is a national organization comprised of individuals with disabilities, family members, and professionals committed to the principles of self-determination: freedom to choose where and with whom one wants to live, as well as what one will do with one's life; authority and control over the dollars necessary for long term supports; designing and providing individual, community-based supports for people with disabilities; and responsibility for both the wise use of public dollars and for contributing to one's community.

E. Hospice Patients Alliance

The Hospice Patients Alliance, Inc. is a charitable nonprofit patient advocacy organization that works to promote excellence in end-of-life care and to protect the rights of patients. It provides information about hospice services, directly assists patients, families and caregivers in resolving difficulties they have with current hospice services, and promotes better quality hospice care.

F. Mouth Magazine/Freedom Clearinghouse

Mouth Magazine, published by Free Hand Press, Inc., is a magazine run by and dedicated to issues concerning people with disabilities. Its mission is to promote the lives and freedoms of all people with disabilities through magazines, books, handbooks, speeches, pamphlets, and electronic media. The mission statement of Freedom Clearinghouse is to publicize and implement the right of people with disabilities to live in the community.

G. National Council on Independent Living

The National Council on Independent Living (NCIL) represents over 700 advocacy organizations and people with disabilities of all types. The independent living philosophy, which NCIL and its members advance, holds that people with disabilities have the right to live with dignity and appropriate supports in their own homes, participate in their communities, and control and make decisions about their lives, regardless of the degree of disability.

H. National Spinal Cord Injury Association

Founded in 1948, the National Spinal Cord Injury Association (NSCIA) is the largest organization in the United States dedicated to improving the quality of life of persons with spinal cord injuries and diseases. The NSCIA's mission is to enable people with spinal cord injuries to make choices and take actions to achieve their highest level of independence and personal fulfillment. Spinal cord injury has been cited as the type of impairment warranting a desire to hasten death. The NSCIA believes that expediting one's death because they have a disability is immoral and unwise, both for society at large and members of the disability community in particular.

I. Self-Advocates Becoming Empowered

Self-Advocates Becoming Empowered is a national organization comprised of and directed by people with developmental disabilities, including intellectual disabilities or mental retardation, cerebral palsy and autism. First established in 1974, Self-Advocates Becoming Empowered now has over 900 chapters in 46 states (known locally as "People First" organizations), with an estimated 20,000 members. Many members have been unnecessarily institutionalized and have experienced discrimination by medical practitioners.

J. Society for Disability Studies

The Society for Disability Studies is an international non-profit organization that promotes the exploration of disability through research, artistic production, and teaching.

K. TASH

TASH (formerly the Association for Persons with Severe Handicaps) is an international advocacy organization of people with disabilities, their families, advocates and professionals in the disability field. It has over 30 chapters covering 37 states and members in 34 nations. TASH has adopted a resolution opposing physician-assisted suicide.[4]

L. World Institute on Disability

The World Institute on Disability (WID) is a nonprofit research, public policy and advocacy center dedicated to promoting the civil rights and full societal inclusion of people with disabilities. WID is governed and staffed by a majority of people with disabilities.

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[4] www.tash.org/resolutions/res02assistedsuicide.htm.

SUMMARY OF ARGUMENT

Amici support the Attorney General's interpretive ruling that assisted suicide is not a "legitimate medical practice" under the Controlled Substances Act, 21 U.S.C. §§ 801-971, and its implementing regulations, 21 C.F.R. § 1306.04(a). When applied only to people with significant or even "terminal" health impairments, Oregon's assisted suicide law encourages the disabled to end their lives – and guarantees such efforts will be successful – while other state laws concurrently discourage non-disabled persons from doing so. Assisted suicide laws deny people with disabilities the benefit of programs and laws that prevent suicide and are the ultimate legal judgment that the life of a person with a disability is not as worthwhile as that of a non-disabled person.

Assisted suicide also raises serious ethical concerns regarding the medical profession's treatment of the disabled. It requires doctors to make difficult, if not impossible, determinations of a person's competency and life expectancy, the consequences of which are both ultimate and irreversible. The availability of assisted suicide also distracts from the determination whether a person's desire to die might be lifted with improved treatment, community-based health care or other measures that improve a person's independence and dignity.

Thus, given the Attorney General's latitude to interpret federal statutes that Congress has authorized him to enforce, *see Chevron U.S.A. v. Natural Resources Defense Council,* 467 U.S. 837, 844 (1982), this difference in treatment, based solely on the presence of a severe disability, justifies the Attorney General's action here. Additionally, Congress and the Attorney General are not precluded from acting to protect the rights of people with disabilities simply because such protection regulates the practice of medicine. The Court of Appeals' erroneous reliance on *Gregory v.*

Ashcroft, 501 U.S. 452 (1991), and its imposition of the "clear statement" rule to an area that is not a "fundamental" state function, unduly impairs Congress' ability to legislate against state infringements on the civil rights of people with disabilities.

ARGUMENT

I. Assisted Suicide Serves No Legitimate Medical Purpose Because It Discriminates Against and Degrades the Lives of People with Disabilities

A. Laws, Programs and Services Operate to Prevent People from Committing Suicide

Suicide is a practice that American society disapproves of and actively discourages through laws and prevention programs. *Washington v. Glucksberg*, 521 U.S. 702, 711 (1997) ("[F]or over 700 years, the Anglo-American common-law tradition has punished or otherwise disapproved of both suicide and assisting suicide."). The U.S. Surgeon General has called suicide "a serious health problem." *The Surgeon General's Call to Action to Prevent Suicide 1999* at 1. Every year, 500,000 people in the United States use emergency room services as a result of suicide attempts. *Id.* In almost every state, helping someone commit suicide is a crime. *Glucksberg,* 521 U.S. at 710-11. In Oregon, intentionally causing or aiding another person to commit suicide is second-degree manslaughter. Or. Rev. Stat. § 163.125. Oregon law also authorizes physical force to prevent someone from committing suicide. Or. Rev. Stat. § 161.205(4).[5] Additionally, many states statutorily mandate

[5] *See also* Ariz. Rev. Stat. § 13-403; Del. Code Ann. tit. 11, § 467; 9 Guam Code Ann. § 7.92; Haw. Rev. Stat. § 703.308; Neb. Rev. Stat. § 28.1412; N.H. Rev. Stat. Ann. § 627.6; N.J. Stat. Ann. § 2C:3-7; N.D. Cent. Code § 12.1-05; 18 Pa. Cons. Stat. § 508; Tenn. Code Ann. § 39-11-613; Wis. Stat. § 939.48.

suicide prevention plans, hotlines, or other intervention programs.[6]

According to the World Health Organization (WHO), depression and anxiety are often associated with suicide and over 80 percent of suicide victims had severe depression. WHO, *World Report on Violence and Health* 192 (2002). Oregon law reflects this assumption that persons who commit suicide do not act rationally. For life insurance purposes, Oregon law creates a presumption against suicide, under the reasoning that "it is common knowledge that sane persons do not ordinarily kill themselves." *Wyckoff v. Mutual Life Ins. Co.,* 147 P.2d 227, 229 (Or. 1944); *see also* Or. Rev. Stat. § 656.310 (for worker's compensation claims, worker's death presumed not to be suicide). Oregon also presumes that the will of one who commits suicide is invalid and the product of a "deranged" mind. *In re Kober's Will,* 285 P. 1032 (Or. 1930).[7]

[6] *See e.g.* Alaska Stat. S§ 44.29.300-44.29.390; Ariz. Rev. Stat. § 36.3415; Ark. Code Ann. § 6-18-1005; Cal. Gov. Code § 53110; Cal.Welf. & Inst. Code §§ 4098 – 4098.5; Conn. Gen. Stat. § 7-294g; 410 Ill. Comp. Stat. 53/5-15; La. Rev. Stat. Ann. § 17.282.4; Md. Code Ann., Health-General § 10-1403(a)(1)(iii); Mass. Ann. Laws ch. 40, § 36C; Minn. Stat. § 146.56; Mo. Rev. Stat. § 630.900; Nev. Rev. Stat. §§ 439.511 – 439.513; N.H. Rev. Stat. § 186.67-a; N.J. Stat. Ann. §§ 30:9A-13 – 30:9A-27; N.D. Cent. Code § 57-40.6-10; Okla. Stat. Ann. §§ 12-101 – 12-105; 24 P.R. Laws Ann. §§ 3241 – 3244; R.I. Gen. Laws § 16-22-14; Va. Code Ann. § 32.1-73.7.

[7] Other ways in which Oregon law discourages suicide include: the exclusion of suicide threats from a state law mandating confidentiality of statements made during counseling sessions, Or. Rev. Stat. § 181.860(8)(a); establishing a statewide team to investigate youth suicides, Or. Rev. Stat. § 418.748; establishing a Youth Suicide Prevention Coordinator, Or. Rev. Stat. § 418.756; and mandating that hospitals refer children who attempt suicide to crisis intervention services, Or. Rev. Stat. § 441.750.

B. The Oregon Assisted Suicide Law Denies People with Disabilities the Benefits of Suicide Prevention Laws and Measures

The Oregon "Death with Dignity" Act, Or. Rev. Stat. §§ 127.800 – 127.995, modifies the assumption that suicide is irrational and undesirable – but only as to persons with "terminal" disabilities or conditions. For these people, Oregon law does not assume that suicide is irrational or a practice that should be discouraged. Rather, the law allows doctors and others to facilitate suicide, an act that would be a crime but for the person's disability. Persons with severe health impairments are therefore denied the benefit of suicide prevention laws and programs. Indeed, state law guarantees their suicide attempts will succeed – unlike those of other persons with suicidal ideations. A practice that the State would otherwise expend public health resources to prevent is instead allowed to occur. This differing response is based solely on a person's disability.[8]

If a state overtly excluded people with "terminal" disabilities from suicide prevention laws and programs, it would undoubtedly violate federal civil rights laws such as the Americans with Disabilities Act, 42 U.S.C. §§ 12132, and Section 504 of the Rehabilitation Act, 29 U.S.C. § 794(a). Yet that is precisely the design and effect of the Oregon assisted-suicide law. A more devastating form of discrimination would be difficult to imagine. By assuming that it is irrational for a non-disabled person to end his or her life, but rational for a disabled person to do so, the law assumes that the non-disabled person's life is intrinsically more valuable and worthwhile than that of a disabled person.

[8] *Amici* do not advocate here for forced treatment or against the right of people with disabilities to refuse treatment. *Amici* include persons with psychiatric disabilities who have been subject to unwanted treatment. *Amici* are concerned solely with the Oregon assisted suicide law's unequal treatment of the disabled. *See* www.mindfreedom.com.

For *amici*, perhaps no other attitude strikes closer to the heart of the disability civil rights movement to which they have dedicated themselves for the past three decades. Central to this movement is the idea that a disabling condition does not inherently diminish one's life; rather, surrounding barriers and prejudices do so. Assisted suicide takes the opposite approach – it gives official sanction to the idea that life with a disabling condition is not worth living.[9] As this Court has recognized:

> The State's interest here [in prohibiting assisted suicide] goes beyond protecting the vulnerable from coercion; it extends to protecting disabled and terminally ill people from prejudice, negative and inaccurate stereotypes, and "societal indifference ..." The State's assisted-suicide ban reflects and reinforces its policy that the lives of terminally ill, disabled and elderly people must be no less valued than the lives of the young and healthy, and that a seriously disabled person's suicidal impulses should be interpreted and treated the same as everyone else's.

Glucksberg, 521 U.S. at 732.

C. Euthanasia and Assisted Suicide Are Part of the Long and Tragic History of Discrimination Against People with Disabilities

Assisted suicide must be seen against the background of the United States' long and tragic history of state-

[9] *See* Carol J. Gill, *Suicidal Intervention for People with Disabilities: A Lesson in Inequality*, 8 Issues in L. & Med. 37 (1992) ("When a culture values human life conditionally, suicide intervention becomes selective. Devalued populations fail to receive rigorous protection, assessment and treatment.")

sanctioned discrimination against the disabled, which five members of the Supreme Court have called "grotesque." *City of Cleburne v. Cleburne Living Center,* 473 U.S. 432, 454-55 & 461 (1985). *Amici*'s experience is that this history continues to haunt the everyday lives and realities of people with disabilities, particularly when making so-called "end-of-life" decisions.

Throughout history, state officials, with the support of the medical community, have authorized the sterilization of people with disabilities. *Buck v. Bell*, 274 U.S. 200, 207 (1927) ("It is better for all the world, if ... society can prevent those who are manifestly unfit from continuing their kind ... Three generations of imbeciles are enough").[10] People with disabilities were placed in "massive custodial institutions ... built to warehouse the retarded for life; the aim was to halt reproduction of the retarded and 'nearly extinguish their race.'" *City of Cleburne*, 473 U.S. at 461-62 (Marshall, J., concurring & dissenting) (citations omitted). The disabled were deemed "uneducable" and excluded *en masse* from public schools. *See School Comm. of Burlington v. Massachusetts Dep't of Educ.*, 471 U.S. 359, 373 (1985). These practices, like Jim Crow laws in the south, were carried out by elected officials with the support of the voters. This did not make them any more legitimate or constitutional.

Euthanasia played a key role in this history. In the 1940s, medical professionals sought the involuntary euthanasia of the severely disabled. In a 1941 presentation to the American Psychiatric Association, which was later

[10] *See also In re Simpson,* 180 N.E. 2d 206 (Ct. Common Pleas Oh. 1962) (ordering sterilization of woman with retardation because of "probability that [her] offspring will be mental'y deficient and become a public charge for most of their lives."); H. Laughlin, *Eugenic Sterilization in the United States* 369 (1922) ("[D]efectives who are practically certain to breed principally defectives, owe a debt to the community that can be discharged only by an adequate guarantee that they shall not contribute to the next generation.").

published in the Association's journal, Dr. Foster Kennedy, the President of the American Neurological Association, stated:

> [T]he place for euthanasia, I believe, is for the completely hopeless defective: nature's mistake; something we hustle out of sight, which should never have been seen at all. These should be relieved of the burden of living ... to allow them to continue such a living is sheer sentimentality, and cruel too; we deny them as much solace as we give our stricken horse. Here we may most kindly kill.

M. Louis Offen, *Dealing with "Defectives": Foster Kennedy and William Lenox on Eugenics,* 61 Neurology 668 (Sept. 2003) (quoting Foster Kennedy, *The Problem of Social Control of the Congenital Defective*, 99 Am. J. Psychiatry 13, 16 (1942)). In 1935, a Nobel Prize-winning fellow at the Rockefeller Institute similarly urged that "sentimental prejudice ... not obstruct the quiet and painless disposition of incurable ... and hopeless lunatics." *The Right to Kill*, Time, Nov. 18, 1935, at 53-54.[11]

Such attitudes, unfortunately, are not completely in the past. Prominent ethicists such as Peter Singer of Princeton University have sanctioned the killing of infants with severe disabilities based on a belief that they will not lead a "good" life and will burden their parents and society. Peter Singer, *Rethinking Life and Death: The Collapse of Our Traditional Ethics* 197-98 (1994). Professor Singer has also written that it is impossible to kill people with severe cognitive disabilities "against their will" "because they are not capable of having a will on such a matter." *Id.*

[11] *See also* Robert J. Lifton, *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (1986).

Amici do not claim that Oregon's assisted suicide law was intended to "extinguish" the disabled. Nevertheless, given this history and the slippery slope it exemplifies, federal safeguards are appropriate and necessary to ensure that euthanasia against the disabled is not, once again, sanctioned as a "legitimate medical practice" as it was for so many years.

D. Assisted Suicide Contravenes Medical Ethics and Practice Because of the Abuse It Poses to People with Disabilities

As this Court has recognized, assisted suicide is contrary to well-established medical ethics. *Glucksberg*, 521 U.S. at 731 (quoting American Medical Association, Code of Ethics § 2.211 (1994)); *see also Vacco v. Quill*, 521 U.S. 793, 801 n.6 (1997) (discussing medical profession's distinction between withholding treatment and assisted suicide). This rejection is firmly grounded in the potential harm the Oregon assisted suicide law poses to the lives of people with disabilities.

1. The Uncertainty of Diagnosing a "Terminal Illness"

First, the diagnosis and prognosis of a "terminal condition" – defined under the Oregon law as a condition likely to cause death within the next six months – is inherently uncertain. Timothy E. Quill *et al., Sounding Board: Care of the Hopelessly Ill*, 327 New Eng. J. Med. 1380, 1381 (Nov. 5, 1992) ("[W]e acknowledge the inexactness of such prognosis [of imminent death]"). Oregon's own reports on the implementation of its assisted suicide law confirm this uncertainty. In 2004, 60 patients were determined "terminally ill" and prescribed lethal medication, but only 35 ingested the medication. Of the 25 who did not, 12 – almost half – were still alive at the end of 2004. One patient who was prescribed medication in 2003,

and thus determined to have less than six months to live, did not ingest the medication and was nevertheless still alive by the end of 2004. Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* 12 (2005).

Assisted suicide has not been limited to persons facing imminent death. In the Netherlands, whose assisted suicide law was a model for Oregon, a governmental report confirmed that many people have been killed who did not have a "terminal" illness. Peter Van der Maas *et al., Euthanasia and Other Medical Decisions Concerning the End of Life*, 338 The Lancet 669, 672 (1991).[12] Similarly, only one in four of the people whom Dr. Jack Kevorkian helped commit suicide had a terminal illness; others simply had physical or neurological disabilities. Lori A. Roscoe *et al., Dr. Jack Kevorkian and Cases of Euthanasia in Oakland County, Michigan, 1990-1998*, 343 New Eng. J. Med. 1735, 1736 (Dec. 7, 2000).

The medical profession's predictions of the capabilities and life spans of people with disabilities have been historically unreliable. As the National Council on Disability has reported, "people with disabilities are aware of enough instances of dramatic mistakes that many of them have a healthy skepticism of medical predictions, particularly as it relates to future life quality." *Assisted Suicide: A Disability Perspective* at 27-28. Evan Kemp, Director of the Equal Employment Opportunity Commission under President George H.W. Bush, wrote:

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[12] Not all such cases involve unintentional misdiagnosis. In one Dutch case, a court acquitted a psychiatrist who helped a physically healthy 50-year old woman – who was unquestionably not terminally ill – commit suicide. The woman had been diagnosed with leukemia and had a history of depression. Herbert Hendin, *Seduced by Death: Doctors, Patients and the Dutch Cure*, 10 Issues in L. & Med. 123, 123-26 (1994).

> As a disabled person, I am especially sensitive to the "quality of life" rationale that is frequently introduced in the debate [over assisted suicide]. For the past 47 years I have lived with a progressive neuromuscular disease that first began to manifest itself when I was 12. My disease, Kugelberg Weylander Syndrome, has no known cure, and I have no hope for "recovery." Upon diagnosis, my parents were informed by the physicians treating me that I would die within two years. Later, another group of physicians was certain that I would live only to the age of 18. Yet here I am at 59, continuing to have an extraordinarily high quality of life.

Evan J. Kemp, *Could You Please Die Now?* Wash. Post, Jan. 5, 1997, at C1.

2. The Law's False Assumption that Suicide is "Rational" When Committed by a Person with a Disability

As the *Glucksberg* Court recognized, "those who attempt suicide – terminally ill or not – often suffer from depression or other mental disorders." 521 U.S. at 730.[13] The Court continued, "Research indicates … that many people who request physician-assisted suicide withdraw that request if their depression and pain are treated." *Id.* For example, a study of cancer patients showed that those with depression were four times more likely to want to die. William Breitbart *et al., Depression, Hopelessness and Desire for Hastened Death in Terminally Ill Patients with Cancer*, 284 JAMA 2907, 2909 (Dec. 13, 2000).

[13] Ninety-five percent of those who commit suicide have been found to have a diagnosable psychiatric illness in the months preceding suicide. Herbert Hendin *et al., Physician-Assisted Suicide: The Dangers of Legalization*, 150 Am. J. Psychiatry 14 (Jan. 1993).

Although the Oregon law mandates that doctors must determine that patients are "not suffering from a psychiatric or psychological disorder or depression causing impaired judgment" before prescribing lethal drugs, and must refer such patients for counseling, *see* Or. Rev. Stat. § 127.825, in practice such determinations are extremely problematic. In a survey of Oregon *psychiatrists*, over half were "not at all confident" they could assess in a single consultation whether a psychiatric condition impaired a person's judgment; only six percent were "very confident." Linda Ganzini *et al., Evaluation of Competence to Consent to Assisted Suicide: Views of Forensic Psychiatrists*, 157 Am. J. Psychiatry 595 (Apr. 2000). This is because such assessments are inherently subjective and unreliable. As one research analysis concluded:

> There is a marked lack of clarity about the goals of mandatory psychiatric assessment in all patients requesting PAS [physician-assisted suicide]. More worryingly, there are no clinical criteria to guide such an assessment – just as there are no criteria to assess the rationality of any person's decision to commit suicide.

Brendan D. Kelly *et al., Euthanasia, Assisted Suicide and Psychiatry: A Pandora's Box*, 181 British J. Psychiatry 278, 279 (2002).

Perhaps for these reasons, counseling referrals in assisted suicide cases under the Oregon law are alarmingly rare. In 2004, only five percent of patients seeking assisted suicide were referred for a psychiatric evaluation. *Seventh Annual Report on Oregon's Death with Dignity Act* at 24. In the Netherlands, whose assisted suicide law similarly asks doctors to determine whether a person's judgment is impaired by a psychiatric disability, only three percent of

assisted suicide patients were so referred. Kelly, *supra* at 278.

3. The Law's False Assumption that Disability Intrinsically Deprives Life of Dignity and Value

Many people identified as candidates for assisted suicide could benefit from supportive care or treatment, such as counseling, pain medication, or in-home personal assistance. These measures lessen their pain and suffering, their perceived burden on family members, or their lack of independence and choice. The National Council on Disability has found that "improving laws, policies, programs and services for people with disabilities ... would go a long way toward assuring that any self-assessment or decision about the quality of life of an individual with a disability would be made in an optimal context of independence, equality of opportunity, full participation, and empowerment." *Assisted Suicide: A Disability Perspective* at 13.

Research demonstrates the lack of this type of assistance and support, rather than any intrinsic aspect of a person's disability, is the primary motivation for suicide. For example, one study found that people who experience serious pain are no more likely to want to kill themselves than those who do not. This finding was attributed to "the quality of pain management" provided to terminal patients in the study. Breitbart, *supra* at 2910. In a study of euthanasia in the Netherlands, only ten of 187 patients listed pain as the reason they wanted to die. Van der Maas, *supra* at 672. Depression is also a condition that can be treated with therapy or counseling, which often leads the patient to withdraw his or her request to die. Kelly, *supra* at 279; Herbert Hendin *et al., Physician-Assisted Suicide: The Dangers of Legalization*, 150 Am. J. Psychiatry 14, 15 (Jan. 1993).

Assisted suicide, however, assumes that a disability or medical condition inherently makes life unworthy of continuation. Its availability causes medical practitioners to ignore other measures, services and modifications that might cause someone to reconsider their desire to die. As a doctor at New York's Memorial Sloan-Kettering Cancer Center has observed, assisted suicide "runs the risk of further devaluing the lives of terminally ill patients and may provide the excuse for society to abrogate its responsibility for their care." Kathleen M. Foley, *Competent Care for the Dying Instead of Physician-Assisted Suicide*, 336 New Eng. J. Med. 54 (Jan. 2, 1997).

The desire to die of people with disabilities is often driven by a temporal or situational depression that arises from the perception that their lives lack value or that they are a burden on their loved ones. In a study of HIV and AIDS patients, one participant said, "I'm still inconveniencing other people who look after me and stuff like that ... No, I'd rather die." Another described himself as "a bag of potatoes to be moved from spot to spot ..." James V. Lavery *et al.*, *Origins of the Desire for Euthanasia and Assisted Suicide in People with HIV-1 or AIDS: A Qualitative Study*, 358 The Lancet 362, 364-64 (Aug. 4, 2001).[14]

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[14] Oregon's experience also confirms these findings. Physicians who administered assisted suicide under the Oregon law were asked whether "end of life concerns" contributed to the patient's desire to die:

> In all cases, physicians reported multiple concerns contributing to the request. Eleven (41%) patients included at least four specific concerns: becoming a burden, losing autonomy, decreasing ability to participate in activities that make life enjoyable, and losing control of bodily functions. Another 15 (56%) patients included at least two or three of these concerns. Most frequently noted across all three years were loss of autonomy ... and participation in activities that make life enjoyable ... Patients have increasingly

Another study linked suicidal ideation to unnecessary institutionalization. It found that most terminally ill patients who have a sense of "fractured dignity" were inpatients, "suggesting that the degree of autonomy and independence that can be maintained in a home setting with community based care, as opposed to care enabled by an institution, is an important mediator of one's sense of dignity." This loss of dignity, and the corresponding feelings of depression and hopelessness, are "strong predictors of desire for death and suicidal ideation ..." Harvey Max Chochinov *et al.*, *Dignity in the Terminally Ill: A Cross-Sectional, Cohort Study*, 360 The Lancet 2026 (Dec. 28, 2002).

These medical findings mirror this Court's recognition of the deleterious effects of institutionalization. In *Olmstead v. L.C.*, 527 U.S. 581 (1999), the Court held that unjustified institutionalization was a form of discrimination under the Americans with Disabilities Act because it "perpetuates unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life" and "severely diminishes the everyday life activities of individuals, including family relations, social contacts, work options, economic independence, educational advancement, and cultural enrichment." *Id.* at 600.

The question how to address the needs that underlie the desire to die, however, is typically lost in the wake of the law's "competency" determination. As one Oregon psychiatrist stated:

> The focus of competence may distract from adequate attention and resources on the

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expressed concern about becoming a burden to family, friends or caregivers.

Oregon Department of Human Services, *Oregon's Death with Dignity Act: Three Years of Legalized Physician-Assisted Suicide* 11-12 (2001).

> person and their circumstances ... we may spend thousands of dollars on assessing competence and little in care directed to the day-to-day life and morale of the person.

Ganzini, *supra* at 600. Another study concluded that the Oregon law's competency determination "do[es] not provide a framework to address social circumstances that contribute to the desire for euthanasia or assisted suicide." Lavery, *supra* at 366.

The case of Kenneth Bergstedt exemplifies how external concerns that could be remedied drive the desire to die for people with disabilities. Mr. Bergstedt, a 30-year old Nevada man with quadriplegia, wanted to die because his father, who cared for him, was himself dying of cancer. Mr. Bergstedt, though not in physical pain, feared he would be institutionalized without his father's support. *See McKay v. Bergstedt,* 801 P.2d 617, 628, 637 (Nev. 1990); Stanley S. Herr, *No Place to Go: Refusal of Life-Sustaining Treatment by Competent Persons with Physical Disabilities*, 8 Issues in L. & Med. 3, 10-13 (1992).

A psychiatric evaluation submitted to the trial court found that Mr. Bergstedt was depressed, but that this was irrelevant because "the quality of life for this man is ... forever profaned by a future which offers no relief and only the possibility of worsening." Herr, *supra* at 12. Based on his poor "quality of life," the Nevada Supreme Court upheld his decision to die. *Bergstedt,* 801 P.2d at 824-25. No consideration was given to measures that might have helped Mr. Bergstedt restore his sense of dignity and independence, such as non-institutional, in-home health care.

A dissenting Nevada Supreme Court Justice observed that "[w]ith this kind of support it is no wonder that he decided to do himself in." *Bergstedt,* 801 P.2d at 637 (Springer, J., dissenting). He added, presciently:

> It is critical that the court not put its judicial stamp of approval on negative stereotypes about disability. This would result if it were to allow the state to assist an individual to die only because he or she had a disability. Judicial decisions which are based on societal prejudices merely reinforce those prejudices, making them even more difficult to eradicate.

Id. at 836.

Because it rests on false assumptions and stereotypes of the disabled, Oregon's assisted suicide law enshrines these debilitating attitudes under the protection of state law.

4. The Difficulty in Ensuring Decisions to Die Are Not Coerced or Made By Others

Finally, evidence exists that some persons killed under assisted suicide laws may "choose" suicide under pressure from others. In the case of Kate Cheney, an 85-year old woman with cancer, her psychologist was concerned that Ms. Cheney was not competent to make the decision to die and that her daughter was unduly pressuring her to choose assisted suicide. The daughter simply obtained an opinion from a second psychologist, who determined Ms. Cheney was competent. Ms. Cheney was accordingly prescribed lethal medication and died on August 29, 1999. Evelyn Hoover Barnett, *Is Mom Capable of Choosing to Die?* The Oregonian, Oct. 16, 1999, at G1-2. A Dutch study confirmed that some people administered lethal drugs in that country did not ask to die. Van der Maas, *supra* at 672.

II. The Attorney General's Determination that Assisted Suicide is Not a "Legitimate Medical Practice" is a Permissible Construction of the Controlled Substances Act

A. The Attorney General's Interpretive Ruling is Entitled to Deference

In *Chevron U.S.A. v. Natural Resources Defense Council,* 467 U.S. 837 (1982), this Court set forth the standard under which courts must defer to an Executive Branch agency's interpretation of a statute. When Congress has authorized the agency to enforce the statute, the court must make a twofold inquiry:

> First … whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter … If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of administrative interpretation. Rather, if a statute is silent or ambiguous with respect to a specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Id. at 842-43.

The Court clarified that "permissible construction" was not "the only one [the agency] permissibly could have adopted … or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Id.* at 843 n.11.

Under this standard, an agency's interpretative rulings "are given controlling weight unless they are arbitrary, capricious or manifestly contrary to the statute." *Id.*; *see also Barnhart v. Walton,* 535 U.S. 212, 218 (2002). Even when this standard has not been applied, this Court has nevertheless relied on "the well-reasoned views of the agencies implementing a statute," which "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *Bragdon v. Abbott,* 524 U.S. 624, 642 (1998) (quoting *Skidmore v. Swift & Co.,* 323 U.S. 134, 139-40 (1944)); *see also Olmstead v. L.C.,* 527 U.S. 581, 598 (1999).

Under the Controlled Substances Act, 21 U.S.C. §§ 801 – 971, Congress authorized the Attorney General to register medical practitioners to dispense controlled substances, 21 U.S.C. § 822(b), and designated the Attorney General as the officer responsible for the Act's enforcement. 21 U.S.C. § 871(a). The Attorney General may revoke such registration if he "determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f). In making this determination, the Attorney General may consider, among other factors, "any conduct which may threaten the public health and safety." *Id.* Although preventing drug abuse is one of Congress' goals under the Act, its plain language does not limit itself to that goal; rather, the Act seeks to prohibit any use of prescription drugs that may have a "detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2).

In 1971, the Attorney General promulgated a regulation under the Act that states that prescriptions for controlled substances are valid only if issued for a "legitimate medical purpose" as part of "professional treatment." 21 C.F.R. § 1306.04(a). This Court has affirmed the validity of this regulation. *United States v. Moore,* 423 U.S. 122, 140 (1975).

Under this regulation, the Attorney General issued an interpretive ruling that assisted suicide is not a "legitimate medical practice" for "treatment" within the meaning of this regulation, thereby rendering any prescriptions made for this purpose invalid. Given the well-documented medical concerns over the harm and invidious discrimination the Oregon assisted suicide law poses to people with disabilities, *see* Sec. I, *supra,* the Attorney General's ruling is undoubtedly a valid interpretation of the Act, which does not specifically foreclose this interpretation. *Chevron,* 467 U.S. at 843; *Barnhart*, 535 U.S. at 218.

B. The "Clear Statement" Rule Does Not Apply to Regulation of the Practice of Medicine

The Court of Appeals avoided this analysis by holding that the Attorney General's directive on prescriptions for assisted suicide "interferes with Oregon's authority to regulate medical care within its borders..." *Oregon v. Ashcroft,* 368 F.3d 1118, 1124 (9th Cir. 2004). Relying on *Gregory v. Ashcroft,* 501 U.S. 452 (1990), the Appeals Court held the Attorney General had infringed on an area of law "traditionally reserved for state authority, such as regulation of medical care." *Id.* at 1125. Thus, the Court of Appeals turned the usual test for deference to agency interpretations of federal law on its head: Congress had to make a "clear statement" that it was prohibiting assisted suicide to authorize the Attorney General to act. Because it had not, the Appeals Court held, the Attorney General's ruling was invalid. *Id.* at 1125-26.

Under *Solid Waste Agency v. Army Corps of Engineers*, 531 U.S. 159 (2001), the "clear statement rule" is applied only when "an administrative interpretation of a statute invokes the outer limits of Congress' power ..." *Id.* at 172. It is clear that prohibiting prescriptions made for the purpose of assisted suicide does not place the Controlled

Substances Act outside the boundaries of Congress' Constitutional authority. Congress has always had the power, under the Commerce Clause, to regulate medication prescribed by doctors. *See Minor v. United States,* 396 U.S. 87, 98 n.13 (1969); *Reina v. United States,* 364 U.S. 507, 511 (1960); *In re Grand Jury Proceedings,* 801 F.2d 1164, 1169 (9th Cir. 1986) ("[T]he Commerce Clause empowers the federal government to regulate prescription drugs"). Indeed, given the magnitude of the discrimination posed by Oregon's assisted suicide law, *Amici* here submit that the Fourteenth Amendment, as well as the Commerce Clause, provides a basis for the Attorney General's interpretive ruling. *Cf. Tennessee v. Lane,* 541 U.S. 509, 124 S. Ct. 1978, 1989-93 (2004); *City of Cleburne,* 473 U.S. at 461 (striking down, on rational-basis grounds, law that prohibited home for people with disabilities).

The Appeals Court's underlying reasoning that regulation of the practice of medical infringes upon "a decision of the most fundamental sort for a sovereign entity," as establishing qualifications for state judges was held to be in *Gregory,* 501 U.S. at 460, is patently flawed. There is no support, legal or otherwise, for the Appeals Court's conclusion that regulating the practice of medicine "go[es] to the heart of representative government." *Id.* at 461 (quoting *Sugarman v. Dougall*, 413 U.S. 634, 647 (1973)). *See e.g. Equal Employment Opportunity Comm'n v. Massachusetts*, 987 F.2d 64, 67 (1st Cir. 1993) (distinguishing *Gregory* because "[t]he Missouri constitutional provision was concerned, *not with regulating health care*, but with ensuring the qualifications of the highest state officials.") (emphasis added).

If any federal restriction on the practice of medicine infringed upon a "fundamental" state function, it would call into question Congress' entire regulatory scheme for prescription medication, which has been in effect for three decades and has been repeatedly upheld and enforced. *See*

Moore, 423 U.S. at 139. Indeed, it is difficult to understand how the practice of medicine could be considered solely a state function, given that the federal government has regulated in this area for at least the past 67 years. *See e.g.* Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-397.

The Court of Appeal's holding is of significant concern to *amici* beyond its implications for assisted suicide. Congress and federal agencies often regulate "medical care" to prevent abuse of or discrimination against people with disabilities. If every decision affecting the medical practice were within a state's sovereign power and subject to the "clear statement" rule, Congress' ability to prohibit states from sanctioning disability discrimination in the medical field would be severely undermined.

For example, in *Olmstead*, this Court held that the unnecessary institutionalization of people with disabilities by states was discrimination under Title II of the Americans with Disabilities Act (ADA). Although Title II's definition of discrimination did not explicitly identify unnecessary institutionalization, the Court relied in part upon the Attorney General's regulations and interpretations of the Act in discerning Congress' intent. 527 U.S. at 598. Although this interfered with a "medical" decision approved under state law (and carried out by the State itself), it was nevertheless understood as appropriate federal action. *Id.* [15]

Similarly, in *Bragdon,* this Court ruled that a patient with HIV could bring a claim under Title III of the ADA against a dentist who refused to serve him because of his disability. 524 U.S. at 647. The Court relied on agency determinations that Congress had intended to cover persons

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[15] *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985), while involving the rights of institutionalized people with disabilities, is distinguishable because it involved a state's waiver of sovereign immunity under the Eleventh Amendment, not the underlying challenged practices in the institution. *Id.* at 242.

with HIV under Title III, which applied to medical practitioners. Although this decision involved Congressional regulation of the practice of dentistry, this Court did not invoke the "clear statement" rule or find that Title III encroached upon a "fundamental" state function. *Id.* at 642.[16]

CONCLUSION

For the foregoing reasons, *amici* respectfully urge this Court to reverse the Court of Appeals' decision and affirm the Attorney General's interpretive ruling.

Respectfully submitted,

Walter J. Kendall III
Professor of Law
THE JOHN MARSHALL LAW SCHOOL
315 South Plymouth Court
Chicago, IL 60604
(312) 987-2377

Max Lapertosa
Counsel of Record
Kenneth M. Walden
Adrienne Detanico, Law Clerk
ACCESS LIVING
614 West Roosevelt Road
Chicago, IL 60630
(312) 253-7000

Counsel for *amici curiae*

May 9, 2005.

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[16] In the District Court below, the defendant dentist challenged application of Title III to him on grounds that "the practice of dental medicine is an area of law reserved to the states, and thus beyond the scope of Congress' Commerce Clause authority." *Abbott v. Bragdon*, 912 F. Supp. 580, 592 (D. Me. 1995), *aff'd.*, 107 F.3d 934 (1st Cir. 1997), *vacated & remanded on other grounds*, 524 U.S. 624 (1998). The Court rejected this proposition and held Congress could regulate defendant's dental practice because it was "an economic enterprise". *Id.* at 593-94 & n.15.

(18)

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In The Supreme Court of the United States

ALBERT GONZALES, ET AL.,
Petitioners,

v.

STATE OF OREGON, ET AL.,
Respondents.

On Petition For A Writ Of Certiorari To The United States Court of Appeals For The Ninth Circuit

BRIEF OF AMICUS CURIAE

National Legal Center for the Medically Dependent & Disabled, Inc., In Support of Petitioners

* James Bopp, Jr.
Thomas J. Marzen
Richard E.Coleson
NATIONAL LEGAL CENTER FOR THE MEDICALLY DEPENDENT & DISABLED, INC.
1 South 6th Street
Terre Haute, IN 47807-3510
(812) 232-2434

* *Counsel of Record*
Counsel for Amicus Curiae

May, 2005

LEGAL ADVANTAGE • 432 Walnut Street • Cincinnati, OH 45202
(800) 581-2252

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTEREST OF AMICUS CURIAE 1

SUMMARY OF THE ARGUMENT 1

ARGUMENT 4

I. Whether Prescribing, Dispensing, or Administering Controlled Substances Is a "Legitimate Medical Purpose" for "Treatment" Is a Determination to Be Made In Accord with a National Standard 6

II. Development of State and Federal Law in the United States Supports the Attorney General's Conclusion that Use of Controlled Substances for Assisted Suicide Is Not a "Legitimate Medical Purpose" for "Treatment". 6

A. *State Statutory Law Supports the Conclusion that Assisted Suicide for Any Reason Is Not A "Legitimate Medical Purpose" for "Treatment"* 6

1. Fourteen (14) States Have Enacted New and Strengthened Prohibitions on Physician-Assisted Suicide Since the Year of Enactment of the Oregon Death With Dignity Act. 7

2. State Legislative and Popular Initiatives to Legalize Physician-Assisted Suicide Through Use of Controlled Substances Have Been Consistently

Rejected, With the Sole Exception of Oregon's Initiatives. 10

B. *State Appellate Courts of Have Uniformly Rejected Any State Right to Use of Controlled Substances for Assisted Suicide* 12

C. *Federal Statutory Law Supports the Conclusion that Assisted Suicide for Any Reason Is Not A "Legitimate Medical Purpose" for "Treatment"* 15

CONCLUSION 17

TABLE OF AUTHORITIES

CASES

Donaldson v. Lungren, 1 Cal. App. 4th 1614, 4 Cal. Rptr. 2d 59 (1992) 13

Kevorkian v. Arnett, 939 F. Supp 725 (C.D. Cal. 1996) . . . 13

Krischer v. McIver, 697 So. 2d 97 (Fla. 1997) 14

Mississippi Band of Choctaw Indians v. Holyfield, 490 U.S.5 43 (1989) 13

People v. Kevorkian, 527 N.W.2d 714 (Mich. 1994), cert. denied sub nom., Kevorkian v. Michigan, 519 U.S. 928 (1996) 13

Sampson v. State of Alaska, 31 P.3d 88 (Alaska 2001) . . . 14

United States v. Daniel, 3 F.3d 775 (4th Cir. 1993), cert. denied, 510 U.S. 1130 (1994) 5

United States v. Moore, 423 U.S. 122, 139 (1975) 5

United States v. Norris, 780 F.2d 1207 (5th Cir. 1986) 5

United States v. Vamos, 797 F.2d 1146 (2d Cir. 1986), cert. denied, 479 U.S. 1036 (1987) 5

Vacco v. Quill, 521 U.S. 793 (1997) 6, 13

Washington v. Glucksberg, 521 U.S. 702 (1997) 3, 13

CONSTITUTIONAL PROVISIONS

Alaska Const., art. I, § 1 14

Alaska Const., art. I, § 22 14

Cal. Const., art. I, §1 13

Fla. Const., art. I, § 23 14

Fla. Const., art. II, § 3 14

FEDERAL STATUTES, REGULATIONS, and RULES

5 U.S.C. §§ 8901 et seq. 16

10 U.S.C. §§ 1071 et seq. 16

21 U.S.C. § 801 16

22 U.S.C. § 2504(e) 16

Indian Health Care Improvement Act, 25 U.S.C. §§ 1601 et seq. 16

Rehabilitation Act of 1973, 29 U.S.C. §794e 17

42 U.S.C. §§ 701 et seq. 16

Controlled Substances Act, 21 U.S.C. § 801 et seq. .. *passim*

42 U.S.C. §§ 1395 et seq. 16

Patient Self-Determination Act of 1970, 42 U.S.C. § 1395cc 17

42 U.S.C. §§ 1396 et seq. 16

42 U.S.C. §§ 1397 et seq. 16

38 U.S.C. §§ 1701 et seq. 16

Legal Services Corporation Act, 42 U.S.C. §§ 2996 et seq. 16

Assisted Suicide Funding Restriction Act of 1997, P.L. 105-12, § 1(a), 111 Stat. 23, 42 U.S.C. § 14401 et seq. 15

42 U.S.C. § 14401(b) 15

42 U.S.C. §§ 14402(d)(1)(A) to (K) 16

42 U.S.C.§ 14402(b) 16

42 U.S.C. § 14402(c) 16

42 U.S.C. at § 14402(d)(2) 16

42 U.S.C. at § 14402(d)(3) 16

42 U.S.C. § 14403 16

42 U.S.C. § 14404(b)(1) 17

42 U.S.C. § 14405 16

42 U.S.C. § 14406 17

42 U.S.C. § 14407 16

42 U.S.C. § 14408 16

Protection and Advocacy for Mentally Ill Individuals Act, 42 U.S.C. §§ 10801 et seq. 17

Developmental Disabilities Assistance and Bill of Rights Act of 2000, 42 U.S.C. §§ 15041 et seq. 17

21 C.F.R. § 1306.04 18

21 C.F.R. § 1306.04(a) 4

U. S. Supreme Court Rule 37.6 1

U.S. Supreme Court Rule 37.3(a) 1

STATE STATUTES

Alaska Stat. § 11.41.120 7

Ark. Code Ann. § 5-10-104 7

Ariz. Rev. Stat. § 13-1103 7

Cal. Penal Code § 401 7

Colo. Rev. Stat. § 18-3-104 7

Conn. Gen. Stat. Ann. § 53a-56 7

D.C. Code Ann. § 22-1807 8
Del. Code Ann. tit. 11, § 645 7
Fla. Stat. § 782.08 7
Ga. Code Ann. §16-5-5 7
Idaho Code § 18-303 8
Iowa Code Ann. § 707A.2 7
Ind. Code Ann. § 35-42-1-2.5 7
Ind. Stat. Ann. §§ 35-42-1-2 to 35-42-1-2.5 9
Kan. Stat. Ann. § 21-3406 7
Kan. Stat. Ann. § 60-4401 et seq. 9
Ky. Rev. Stat. Ann. § 216.302 7
Ky. Rev. Stat. Ann. § 216.306 9
La. Rev. Stat. Ann. § 14:32.12 7
Md. Criminal Law Code Ann. § 3-101 to § 3-104 9
Me. Rev. Stat. Ann. tit. 17-A, § 204 7
Mich. Comp. Laws Ann. § 750.329a 9
Minn. Stat. Ann. § 609.215 ..... 7, 9
Mo. Rev. Stat. § 565.023 7
Miss. Code Ann. § 97-3-49 7
Mont. Code Ann. § 45-5-105 7
Neb. Rev. Stat. Ann. § 28-307 7
N.H. Rev. Stat. Ann. § 630:4 7
N.J. Stat. Ann. § 2C:11-6 7

N.M. Stat. Ann. § 30-2-4 7
N.Y. Penal Law § 125.15 ..... 7, 8
N.D. Cent. Code § 12.1-16-04 8
N.D. Cent. Code § 12.1-16-05, § 12.1-16-07 9
Oh. Rev. Code § 3795.01 to 3795.03 9
Okla. Stat. tit. 63, §§ 3141.1 to 3141.8 8
Okla. Stat. tit. 63, §§ 3141.5 to 3141.6 10
Death with Dignity Act, Or. Rev. Stat. §§ 127.800 et seq. (2003) ..... *passim*
18 Pa. Cons. Stat. § 2505 8
R.I. Gen. Laws § 11-60-1 to -5 8
R.I. Gen. Laws § 11-60-5 10
S.C. Code Ann.§ 16-3-1090 ..... 8, 10
S.D. Codified Laws § 22-16-37 8
S.D. Codified Laws § 22-16-37.2 to -37.3 10
Tenn. Code Ann. § 39-13-216 ..... 8, 9
Tex. Penal Code § 22.08 8
Va. Code § 8.01-662.1 9
Wash. Rev. Code. Ann. § 9A.36.0608 8
Wash. Laws, ch. 98, 10 (1992) 11
Wash. Rev. Code § 70.122.100 11
Wis. Stat. § 940.12 8

OTHER AUTHORITIES

Federal Register, 66 Fed. Reg. 56,607 (2001) 4

James Bopp, Jr. & Richard E. Coleson, "Three Strikes: Is an Assisted Suicide Right Out?" 15 Issues in Law & Med. 3 (1999) 14

William Claiborne & Edward Walsh, "Mich. Assisted-Suicide Initiative Defeated," Wash. Post, Nov. 4, 1998 12

Virginia Ellis & Paul Jacobs, "'Tax-the-Rich' Plan Put Hex on Welfare Cutbacks," L.A. Times, Nov. 5, 1992 11

Nat Hentoff, "Time is running out," Washington Times, Jan. 1, 2001 12

Jane Gross, "The 1991 Election: Euthanasia; Voters Turn Down Mercy Killing Idea," N.Y. Times, Nov. 7, 1991 11

Frank Jones, "Euthanasia Boosters Aim to Kill Our Compassion," Toronto Star, Nov. 9, 1992 11

Thomas J. Marzen, Mary K. O'Dowd, Daniel Crone & Thomas J. Balch, "Suicide: A Constitutional Right?" 24 Duquesne L. Rev. 1 (1985) 8

Ben Macintyre, "Voters Hold Sway on Life and Death," The Times, Nov. 3, 1992 11

PR Newswire, "AMA Applauds Defeat of Maine Assisted Suicide Referendum," November 8, 2000, Wednesday 12

INTEREST OF AMICUS CURIAE[1]

The National Legal Center for the Medically Dependent & Disabled, Inc., is a non-for-profit, Indiana corporation formed as a public interest law firm dedicated to the protection of the medical treatment rights of persons with disabilities. Since its inception in 1984, the National Legal Center has litigated numerous cases involving withholding and withdrawing life-sustaining medical treatment and care and has been involved in several cases involving assisted suicide. It opposes assisted suicide and euthanasia as contrary to rights and interests of persons with disabilities and who rely on medical treatment and care for continued survival. The National Legal Center publishes a scholarly journal, *Issues in Law and Medicine*.

SUMMARY OF THE ARGUMENT

Both the present state of law and the strong trend of American law since 1994 – when the Oregon Death with Dignity Act ("DWDA") legalizing physician-assisted suicide using controlled substances was enacted – supports the Attorney General's conclusion that using controlled substances for assisted suicide is not a "legitimate medical purpose" for "treatment" within the meaning of the Controlled Substances Act ("CSA") and its implementing regulations.

Because there is no indication to the contrary in the plain language of the CSA, the CSA is properly interpreted to have uniform application throughout the United States and in accord

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[1] **U. S. Supreme Court Rule 37.6**: Amicus Curiae discloses that (1) no counsel for a party authored this brief in whole or in part, and (2) a partial monetary contribution was made toward the preparation or submission of this brief by the Alliance Defense Fund. **U.S. Supreme Court Rule 37.3(a):** Petitioners and Respondents consented to the filing of this brief. Consent letters have been provided to the Clerk of this Court.

with the standard of practice throughout the United States. The Attorney General was thus fully warranted in concluding that a nationwide standard should govern his determination of what constitutes a legitimate medical purpose without regard to Oregon's anomalous law sanctioning assisted suicide with controlled substances.

Just as when this Court held in 1997 that there is no federal constitutional right to physician-assisted suicide, it remains the case the assisted suicide is crime in almost all the States. At present, thirty-four (34) States criminalize by statute assisted suicide through use of any means, including controlled substances. Other States continue to prohibit the practice as a common law crime or, potentially, as a form of aiding or abetting a homicide. Still others provide statutory civil remedies and professional penalties for any assisted suicide. No state other than Oregon has explicitly sanctioned assisted suicide by statute.

Since Oregon enacted the DWDA in 1994, fourteen (14) states have enacted statutes that specifically criminalize assisted suicide or provide for new or enhanced civil remedies or professional penalties for assisted suicide. Six (6) states enacted prohibitions on assisted suicide; eight (8) states added civil remedies and professional penalties to their criminal statutes. Thus, by a ratio of 14-1, states have acted to increase opposition to assisted suicide since the Oregon DWDA was enacted.

No proposal to legalize physician-assisted suicide has passed either house of any state legislature. Moreover, two (2) states – California and Washington – rejected voter initiatives to legalize physician-assisted suicide using controlled substances prior to 1994, when Oregon enacted the DWDA by voter initiative. Since 1994, two (2) states – Michigan and Maine – have rejected voter initiatives proposing statutes virtually identical to the Oregon DWDA. Neither the legislative nor initiative process has

warranted any substantial support for use of controlled substances for assisting suicide as a legitimate medical practice.

Similarly, no state court of final jurisdiction has held that there is any legal right under state constitutions to physician-assisted suicide using controlled substances. The Supreme Courts of Florida and Alaska, as well as the California Court of Appeals, have specifically rejected such claims. The Michigan Supreme Court rejected a similar claim based on federal constitutional grounds.

Finally, Congress has enacted comprehensive legislation through the Assisted Suicide Funding Restriction Act of 1997 prohibiting the use of any federal funds, facilities, or employees to support assistance in suicide through use of any means. It forbids use of federal funds in any federal health care program for this purpose, and it forbids grants or support to any program that supports the practice. The ban applies to all subsequent legislation and to allocations made to the District of Columbia.

The Act also forbids all federal legal and other advocacy programs from supporting or advocating assisted suicide. It provides that no federal statute should be construed to compel health care providers information on assisted suicide nor impose any requirement to provide such a service.

In sum, the state legislatures, state initiative processes, state courts, and Congress strongly support the Attorney General's conclusion that use of controlled substances for assisting in suicide is not a legitimate medical practice. Moreover, the clear trend in American law rejects legitimacy of the practice. If the Oregon DWDA is an experiment in the laboratory of the states, it is an experiment that has failed.

ARGUMENT

The purpose of this brief is to demonstrate that development of state and federal law on assisted suicide since the 1994 enactment of the Oregon "Death with Dignity Act, Or. Rev. Stat. §§ 127.800 *et seq.* (2003) ("DWDA"), demonstrates that Oregon's statute legalizing assisted suicide remains a sole aberration in American law. Indeed, there is a strong trend in American law *against* permitting assisted suicide evidenced by increased numbers state and federal laws banning, prohibiting governmental funding and facilitation of, and providing new penalties for the practice. As such, the Attorney General is fully warranted in concluding that dispensing, prescribing, and administering controlled substances for assisted suicide is not recognized as a "legitimate medical purpose" for "treatment," 21 C.F.R. § 1306.04(a), within the United States.

I. Whether Prescribing, Dispensing, or Administering Controlled Substances Is a "Legitimate Medical Purpose" for "Treatment" Is a Determination to Be Made In Accord with a National Standard.

At issue in this case is an interpretative rule issued by the Attorney General of the United States on November 9, 2001, in the *Federal Register* (66 Fed. Reg. 56,607 (2001)). Pet. App. 110a-105a. The rule provided that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04," an implementing regulation of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"). Pet. App. at 102a. The Attorney General thus concluded that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." *Id.*

In 1994, Oregon enacted a law legalizing physician assisted suicide by use of controlled substances through the Oregon DWDA. Nevertheless, the Attorney General's rule provided that

his conclusion "applied regardless of whether state law authorizes or permits such conduct by practitioners or others." Pet. App. at 102a. Thus, the Attorney General's rule would render prescribing, dispensing, and administering federally controlled substances for assisted suicide contrary to the CSA, even though the Oregon DWDA or some other future state law legalizes or allows this practice.

Since there is no indication in its plain language to the contrary, the CSA was intended to have uniform application throughout the United States, not subject to the various policy views that prevail in individual states or locales. *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 43, 47 (1989) (without clear indication to the contrary, Congress does not enact a statute dependent on state law). The Attorney General was thus fully warranted in adopting a uniform rule that did not take into account Oregon's anomalous decision to permit assisted suicide using controlled substances. He was fully warranted in concluding that use of controlled drugs to assist persons to commit suicide is not a "legitimate medical purpose" or for "treatment" within the meaning of the CSA and its implementing regulations.

That Oregon has legalized use of federally controlled drugs for assisted suicide is irrelevant to the Attorney General's authoritative interpretation of the CSA. The standard of medical practice under the CSA is that which is "in accordance with the standard of medical practice generally recognized and accepted in the United States." *United States v. Moore*, 423 U.S. 122, 139 (1975) (quoting jury instructions with approval). *See also United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986), *cert. denied*, 479 U.S. 1036 (1987) (standard of medical practice is that "generally recognized in the United States"); *United States v. Norris*, 780 F.2d 1207, 1209 & n.2 (5th Cir. 1986 (same); *United States v. Daniel*, 3 F.3d 775, 778 (4th Cir. 1993), *cert. denied*, 510 U.S. 1130 (1994) (same).

Any other standard would render the CSA virtually meaningless and unenforceable. Local or state medical practice might dictate a nearly limitless number of standards under which physicians and pharmacists might operate in accord with local practice and custom, state legislation, or both.

II. Development of State and Federal Law in the United States Supports the Attorney General's Conclusion that Use of Controlled Substances for Assisted Suicide Is Not a "Legitimate Medical Purpose" for "Treatment."

In holding that there is no federal constitutional right to physician-assisted suicide, this Court observed "that in almost every State . . . it is a crime to assist a suicide." *Washington v. Glucksberg*, 521 U.S. 702, 710 (1997). Nothing has changed in this regard since 1997. Nor has any State legalized assisted suicide since 1994 when Oregon legalized the practice through the use of controlled substances. To the contrary, several states have explicitly prohibited the practice and increased penalties attached to it; two state supreme courts have upheld the bans on assisted suicide under their respective constitutions; two voter initiatives to legalize the practice were defeated; the federal government enacted a comprehensive ban on the use of its funds, facilities, or funded agencies from involvement in the practice. In sum, the present state and clear trend of the law of assisted suicide strongly supports the Attorney General's conclusion that use of controlled substances for this purpose is not a legitimate medical practice or form of treatment in the United States.

A. *State Statutory Law Supports the Conclusion that Assisted Suicide for Any Reason Is Not A "Legitimate Medical Purpose" for "Treatment."*

The Oregon DWDA legalizing use of controlled substances for assisted suicide is a singular aberration that cannot justify turning enforcement of the CSA on its head, demanding that the

Oregon tail wag the federal dog. No other state has followed the Oregon lead. To the contrary, they have proceeding in the opposite direction, acting to affirm and strengthen opposition to use of controlled substances for such a purpose.

1. Fourteen (14) States Have Enacted New and Strengthened Prohibitions on Physician-Assisted Suicide Since the Year of Enactment of the Oregon Death With Dignity Act.

At present, thirty-four (34) States by statute explicitly criminalize assisted suicide for any reason, in any circumstance, and through the use of any means. **Alaska**: Alaska Stat. § 11.41.120; **Arkansas**: Ark. Code Ann. § 5-10-104; **Arizona**: Ariz. Rev. Stat. § 13-1103; **California**: Cal. Penal Code § 401; **Colorado**: Colo. Rev. Stat. § 18-3-104; **Connecticut**: Conn. Gen. Stat. Ann. § 53a-56; **Delaware**: Del. Code Ann. tit. 11, § 645; **Florida**: Fla. Stat. § 782.08; **Georgia**: Ga. Code Ann. §16-5-5; **Iowa**: Iowa Code Ann. § 707A.2; **Indiana**: Ind. Code Ann. § 35-42-1-2.5; **Kansas**: Kan. Stat. Ann. § 21-3406; **Kentucky**: Ky. Rev. Stat. Ann. § 216.302; **Louisiana**: La. Rev. Stat. Ann. § 14:32.12; **Maine**: Me. Rev. Stat. Ann. tit. 17-A, § 204; **Minnesota**: Minn. Stat. Ann. § 609.215; **Missouri**: Mo. Rev. Stat. § 565.023; **Mississippi**: Miss. Code Ann. § 97-3-49; **Montana**: Mont. Code Ann. § 45-5-105; **Nebraska**: Neb. Rev. Stat. Ann. § 28-307; **New Hampshire**: N.H. Rev. Stat. Ann. § 630:4; **New Jersey**: N.J. Stat. Ann. § 2C:11-6; **New Mexico**: N.M. Stat. Ann. § 30-2-4; **New York**: N.Y. Penal Law § 125.15; **North Dakota**: N.D. Cent. Code § 12.1-16-04; **Oklahoma**: Okla. Stat. tit. 63, §§ 3141.1 to 3141.8; **Pennsylvania**: 18 Pa. Cons. Stat. § 2505; **Rhode Island**: R.I. Gen. Laws § 11-60-1 to -5; **South Carolina**: S.C. Code Ann.§ 16-3-1090; **South Dakota**: S.D. Codified Laws § 22-16-37; **Tennessee**: Tenn. Code Ann. § 39-13-216; **Texas**: Tex. Penal Code § 22.08; **Washington**: Wash. Rev. Code. Ann. § 9A.36.060; **Wisconsin**: Wis. Stat. § 940.12.

Other jurisdictions have no specific statute penalizing assisted suicide, but continue to recognize common law crimes, including assisted suicide, or may punish assisting in suicide as a form of aiding or abetting a homicide. *See, e.g.*, **Idaho:** Idaho Code § 18-303 (recognizing common law offenses as crimes); **Washington D.C.:** D.C. Code Ann. § 22-1807 (same). *See also* Thomas J. Marzen, Mary K. O'Dowd, Daniel Crone & Thomas J. Balch, "Suicide: A Constitutional Right?" 24 Duquesne L. Rev. 1, 56-100 (1985) (discussing English/American law of suicide in absence of statute).[2]

Crucially, no State has liberalized its assisted suicide statutes or common law since 1994 when the Oregon DWDA was enacted. To the contrary, fourteen (14) States have either enacted explicit statutory bans on assisted suicide, including physician-assisted suicide, that did not exist before 1994 or strengthened anti-assisted suicide laws already on the books by adding provisions warranting revocation of health care professional licenses, compensatory damages, punitive damages, and injunctive relief for assisting in suicide.

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[2]Ten (10) states have no case or statutory law that specifically penalizes or otherwise prohibits assisted suicide: **Alabama, Hawaii, Illinois, Massachusetts, North Carolina, Nevada, Utah, Vermont, West Virginia,** and **Wyoming**. However, assisted suicides probably cannot be safely performed and are certainly not openly performed in these states without specific statutory authorization like that of Oregon's DWDA in view of the lengthy common law history opposed to assisted suicide, the possibility that homicide statutes might be applied, continuing medical ethical condemnations of the practice and the criminal and civil law implications this entails, the need to preserve the doctrine of transferred intent in this context so that an crime exists when third parties are injured or killed by suicides, and the fact that suicide and assisted suicide everywhere remain against public policy (as evidenced by such practices as police interference in suicides and the universal presumption that those who would attempt suicide are mentally or emotionally incompetent as "dangers to themselves or others").

Thus, six (6) states have enacted new prohibitions on assisted suicide since 1994. **Indiana:** Ind. Stat. Ann. §§ 35-42-1-2 to 35-42-1-2.5 (effective 1994) (criminal ban); **Maryland:** Md. Criminal Law Code Ann. § 3-101 to § 3-104 (adopted 1999)(criminal ban); **Michigan:** Mich. Comp. Laws Ann. § 750.329a (adopted September 1, 1998)(criminal ban); **Ohio:** Oh. Rev. Code § 3795.01 to 3795.03 (adopted 2002)(revoking health care professional licenses and sanctioning civil injunctive relief); **Tennessee:** Tenn. Code Ann. § 39-13-216 (enacted 1993, effective 1994)(sanctioning injunctive, compensatory, and punitive relief against a person violating or about to violate Tennessee's criminal assisted suicide statute); **Virginia:** Va. Code § 8.01-662.1 (adopted 1998)(prohibiting as against public policy and sanctioning civil damages and relief).

In addition, since 1994, eight (8) States have enacted provisions strengthening pre-1994 statutory prohibitions on assisted suicide. **Kansas:** Kan. Stat. Ann. § 60-4401 *et seq.* (amended July 1, 1998)(providing injunctive relief as well as compensatory and exemplary damages against anyone violating or attempting to violate Kansas' assisted suicide law); **Kentucky:** Ky. Rev. Stat. Ann. § 216.306 (amended April 8, 1994)(affording injunctive relief against a person reasonably believed to be about to violate Kentucky's assisted suicide law); **Minnesota:** Minn. Stat. Ann. § 609.215 (amended 1995)(offering injunctive relief, compensatory and punitive damages, and attorney's fees against anyone violating or attempting to violate Minnesota's assisted suicide law); **North Dakota:** N.D. Cent. Code § 12.1-16-05, § 12.1-16-07 (amended August 1, 1999)(establishing injunctive relief and compensatory and punitive damages against a person who has violated or is reasonably believed to be about to violate North Dakota's assisted suicide law); **Oklahoma:** Okla. Stat. tit. 63, §§ 3141.5 to 3141.6 (July 1, 2001)(creating injunctive relief and compensatory and punitive damages against a person for

violating or attempting to violate Oklahoma's assisted suicide law); **Rhode Island:** R.I. Gen. Laws § 11-60-5 (amended 1996)(permitting the attorney general to seek injunctive relief against any one believed to be about to violate Rhode Island's assisted suicide law); **South Carolina:** S.C. Code Ann. § 16-3-1090 (amended June 30, 1998)(granting injunctive relief against anyone reasonably believe to be about to violate or to be in the course of violating South Carolina's assisted suicide law); **South Dakota:** S.D. Codified Laws § 22-16-37.2 to -37.3 (amended March 21, 1997)(allowing injunctive relief as well as both compensatory and punitive damages to be sought against a person violating or about to violate South Dakota's assisted suicide law).

Thus, not only does an overwhelming majority of States certainly continue to ban physician-assisted suicide, the margin of majority has substantially increased since 1994 when Oregon legalized the practice. Moreover, by a ratio of 14 to 1, the States have acted to sanction and further strengthen bans on physician-assisted suicide since Oregon lifted its ban. It is clear that the States do not regard and, moreover, increasingly reject physician-assisted suicide through use of controlled substances as a legitimate medical purpose for treatment.

2. State Legislative and Popular Initiatives to Legalize Physician-Assisted Suicide Through Use of Controlled Substances Have Been Consistently Rejected, With the Sole Exception of Oregon's Initiatives.

After diligent research, your Amicus could discover no instance in any State in which any specific statutory proposal to legalize or authorize physician-assisted suicide through the use of controlled substances – or, indeed, to legalize or authorize assisted suicide through use of any means – has been enacted by even one body of any State legislature. Quit simply, there is not

and has not been any substantial state legislative support for any such proposal.

The Oregon DWDA, the sole instance in which assisted suicide has been legalized in the United States, was enacted and reaffirmed by popular initiative, not legislative action. Yet Oregon's endorsement of the practice by initiative is also a singular anomaly. Four other state initiatives have rejected legalization of physician-assisted suicide.

The State of Washington rejected the practice, which had been offered by ballot proposal and introduced through Washington's initiative process in the November 1991 elections. Washington Initiative 119 would have legalized physician "aid-in-dying" for terminally-ill competent patients. It was defeated by fifty-four (54) percent to forty-six (46) percent. *See* Jane Gross, "The 1991 Election: Euthanasia; Voters Turn Down Mercy Killing Idea," N.Y. TIMES, Nov. 7, 1991, at B16. Washington's Natural Death Act was then legislatively amended to expressly reject physician-assisted suicide. Wash. Laws, ch. 98, 10 (1992); Wash. Rev. Code § 70.122.100.

California's Proposition 16, a ballot initiative that would have legalized physician "aid-in-dying," was defeated in the November 1992 election by a majority of fifty-four (54) percent to forty-six (46) percent. *See* Ben Macintyre, "Voters Hold Sway on Life and Death," THE TIMES, Nov. 3, 1992, at 10; Virginia Ellis & Paul Jacobs, "'Tax-the-Rich' Plan Put Hex on Welfare Cutbacks," L.A. TIMES, Nov. 5, 1992, at A3; Frank Jones, "Euthanasia Boosters Aim to Kill Our Compassion," TORONTO STAR, Nov. 9, 1992, at D1.

The 1994 enactment of Oregon's DWDA interrupted, but did not alter, the trend. To the contrary, subsequent ballot initiatives strongly reaffirmed rejection of physician-assisted suicide.

In the 1998 election, a Michigan ballot initiative that would have enacted a statute virtually identical to the Oregon DWDA was defeated by a 2-1 ratio. *See* William Claiborne & Edward Walsh, "Mich. Assisted-Suicide Initiative Defeated," WASH. POST, Nov. 4, 1998, at A34.

Again, in the 2000 election, a Maine ballot initiative proposing a law virtually identical to Oregon's, was defeated by margin of 51.3 percent to 48.7 percent. *See* PR Newswire, "AMA Applauds Defeat of Maine Assisted Suicide Referendum," November 8, 2000, Wednesday; Nat Hentoff, "Time is running out," WASHINGTON TIMES, Jan. 1, 2001, at A15.

Thus, no legislature in the United States has even seriously entertained any law legalizing assisted suicide, whether or not with the use of controlled substances. No State other than Oregon has enacted such legislation through voter initiative – and the voters of four (4) States have specifically rejected such legislation, with Michigan and Maine voters rejecting it after Oregon's DWDA permitting physician-assisted suicide with controlled drugs was enacted in 1994. There is no legislative or substantial voter support for the notion that use of controlled drugs for physician-assisted suicide is a "legitimate medical purpose." If the Oregon DWDA is to be regarded as experiment in the laboratory of the states, then it is an experiment that has failed.

B. *State Appellate Courts of Have Uniformly Rejected Any Right to Use of Controlled Substances for Assisted Suicide.*

Recognition under state constitutions of any right to assisted suicide or physician-assisted suicide with the use of controlled substances has been rejected by courts of every State in which suit has been brought. No state court has held that such a right or privilege exists under state law.

In 1992, a California Court of Appeals held that there is no right to assisted suicide under either the U.S. Constitution or the right of privacy of article I, section 1 of the California Constitution in *Donaldson v. Lungren*, 1 Cal. App. 4th 1614, 4 Cal. Rptr. 2d 59 (1992). Donaldson sought physician assistance in dying in order to pursue and facilitate cryogenic suspension. 1 Cal. App. 4th at 1618; 4 Cal. Rptr. 2d at 60. The court rejected Donaldson's claim under both the U.S. and California Constitutions, noting that, "No statute or judicial opinion countenances Donaldson's decision to consent to be murdered or to commit suicide with the assistance of others." 1 Cal. App. 4th at 1622; 4 Cal. Rptr. 2d at 63. "We cannot expand the nature of Donaldson's right of privacy to provide a protective shield for third persons who end his life." *Id. See also Kevorkian v. Arnett*, 939 F. Supp 725 (C.D. Cal. 1996) (there is no persuasive authority to believe that the California Supreme Court would hold contrary to *Donaldson* when directly presented with the issue).

There have been two direct challenges to state anti-assisted suicide statutes based on claimed state constitutional rights to physician-assisted suicide using controlled substances.[3] The Supreme Courts of both states – Florida and Alaska – rejected recognition of any such right.

In *Krischer v. McIver*, 697 So. 2d 97 (Fla. 1997), the Florida Supreme Court rejected the concept that there is "no distinction between the right to refuse medical treatment and the right to commit physician-assisted suicide through self administration of

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[3]Prior to *Washington v. Glucksberg* and *Vacco v. Quill*, 521 U.S. 793 (1997), in which this Court held there was no federal substantive or equal protection right to assisted suicide, the Michigan Supreme Court held that the U.S. Constitution did not recognize a right to physician-assisted suicide in *People v. Kevorkian*, 527 N.W.2d 714 (Mich. 1994), *cert. denied sub nom., Kevorkian v. Michigan*, 519 U.S. 928 (1996). No state constitutional right was asserted in this case.

a lethal does of medication." *Id.* at 102. In such a circumstance, the person "will not die from the complications of his illness. Rather, a physician will assist him in administering a 'death-producing agent' with the intent of causing certain death." *Id.* at 103. The case had been brought under Florida's explicit constitutional "right to privacy" provision of art. I, § 23, Fla. Const. The Florida Supreme Court rejected its application, observing that "[b]y broadly construing the privacy amendment to include the right to assisted suicide, we would run the risk of arrogating to ourselves those powers to make social policy that as a constitutional matter belong only to the legislature." 697 So. 2d at 104 (*citing* art. II, § 3, Fla. Const. (separation of powers)). [4]

In *Sampson v. State of Alaska*, 31 P.3d 88 (Alaska 2001), the Alaska Supreme Court held that there is no right to receive "prescribed medication to self-administer for the purpose of hastening death, " *id.* at 90, under the explicit right to privacy provision (art. I, § 22) or the liberty and equal protection provision (art. I, §1) of the Alaska Constitution. As the decided, "We hold that the right to physician-assisted suicided is no implicit in text, context, or history of the Alaska Constitution's liberty and privacy clauses." *Id.* at 98. "[T]hey do not require an exemption to Alaska's manslaughter statute that would provide for physician-assisted suicide." *Id.* The Alaska Court also upheld the physician-assisted suicide ban, observing that death that follows omission of medical treatment is distinguished from death from assisted suicide because, "when a physician assists a terminal patient by prescribing medication to hasten the patient's death, the death is caused by the patient and is abetted by the physician's affirmative actions." *Id.* at 99.

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[4]For a comprehensive overview of developments in the law of assisted suicide through *Krischer v. McIver*, *see* James Bopp, Jr. & Richard E. Coleson, "Three Strikes: Is an Assisted Suicide Right Out?" 15 ISSUES IN LAW & MED. 3 (1999).

In effect, therefore, all the state courts of final jurisdiction to have addressed the matter have concluded that prescribing, dispensing, and administering a controlled substance for the purpose of assisting in suicide is no different than providing a person with a gun or rope with knowledge and intent that the person will use it to commit suicide. They agree with the Attorney General that this is not a "legitimate medical purpose" for treatment.

C. *Federal Statutory Law Supports the Conclusion that Assisted Suicide for Any Reason Is Not A "Legitimate Medical Purpose" for "Treatment."*

Congress could not be more clearly opposed to any national participation in assisted suicide practices. The "Assisted Suicide Funding Restriction Act of 1997," P.L. 105-12, § 1(a), 111 Stat. 23, 42 U.S.C. § 14401 *et seq.* (the "Act"), with the "principal purpose . . . to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing)the suicide, euthanasia, or mercy killing of any individual." *Id.* at § 14401(b).

The Act is comprehensive in scope. It provides that no federal funds whatever may be used – whether directly or indirectly, in whole or in part, or through any matching or health benefit – for assisted suicide, euthanasia, or mercy killing. *Id.* at § 14402(b). It forbids such practices in any federal facility or by any federal employee. *Id.* at § 14402(c).

The Act itemizes the federal programs to which these restrictions apply to include: the Medicare program (42 U.S.C. §§ 1395 *et seq.*), the Medicaid program (42 U.S.C. §§ 1396 *et seq.*), Title XX social services block grants (42 U.S.C. §§ 1397 *et seq.*), the maternal and child health block grant program (42 U.S.C. §§ 701 *et seq.*), the Public Health Service Act, the Indian

Health Care Improvement Act (25 U.S.C. §§ 1601 *et seq.*), the federal employees health benefits program (5 U.S.C. §§ 8901 *et seq.*), the military health care system, including TRICARE and CHAMPUS programs (10 U.S.C. §§ 1071 *et seq.*), veterans medical care (38 U.S.C. §§ 1701 *et seq.*), health services for Peace Corps volunteers (22 U.S.C. § 2504(e)), and medical services for federal prisoners. 42 U.S.C. at §§ 14402(d)(1)(A) to (K).

The Act explicitly forbids such practices in facilities or by employees of the military health care system (operating under 10 U.S.C. §§ 1071 *et seq.*), the veterans health care system or the Public Health Service. 42 U.S.C. at § 14402(d)(2). The lists are deemed nonexclusive, *id.* at § 14402(d)(3), and the Act supercedes any subsequent federal law unless it specifically otherwise provides. *Id.* at § 14408. It explicitly forbids federal grants or support of any program or service that has the purpose of assisting in suicide, euthanasia, or mercy killing. *Id.* at §§ 14403 and 14405. The Act applies to all funded activities in the District of Columbia. *Id.* at § 14407.

Moreover, the Act forbids any federal advocacy program from assisting, supporting, or providing any service that includes assisting in suicide, euthanasia, or mercy killing. It specifically forbids any such participation by: protection and advocacy systems funded under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. §§ 15041 *et seq.*), protection and advocacy systems funded under the Protection and Advocacy for Mentally Ill Individuals Act (42 U.S.C. §§ 10801 *et seq.*), protection and advocacy systems funded under the Rehabilitation Act of 1973 (29 U.S.C. §794e), ombudsman programs funded under the Older Americans Act of 1965, and legal assistance programs funded under the Legal Services Corporation Act (42 U.S.C. §§ 2996 *et seq.* 42 U.S.C. § 14404(b)(1).

Finally, the Act provides that various requirements of federal law requiring that patients be informed of their treatment rights, including the Patient Self-Determination Act of 1970 (42 U.S.C. § 1395cc), neither require that patients be informed of any "right" to assisted suicide, euthanasia, or mercy killing nor impose a requirement that directs performance of assisted suicide, euthanasia, or mercy killing. 42 U.S.C. § 14406.

In sum, the policy of the federal government of the United States is uniformly and absolutely opposed to assisted suicide through the use of any means, including controlled substances. It is a national policy fully consistent with that of the several States, with the sole, completely anomalous exception of the State of Oregon. There is no basis in federal law to conclude that the use of controlled substances for assisted suicide is, under any circumstances, a "legitimate medical purpose" for "treatment."

CONCLUSION

For the foregoing reasons, Amicus Curiae National Legal Center for the Medically Dependent & Disabled, Inc., to reverse the decisions of the courts below and uphold that the interpretative rule issued by the Attorney General of the United States on November 9, 2001, providing that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. § 1306.04, an implementing regulation of the Controlled Substances Act, 21 U.S.C. § 801.

Respectfully submitted,

James Bopp, Jr.
Counsel of Record
Thomas J. Marzen
Richard E. Coleson
NATIONAL LEGAL CENTER FOR THE MEDICALLY DEPENDENT & DISABLED, INC.
1 South 6th Street
Terre Haute, IN 47807-3510
(812) 232-2434
Counsel for Amicus Curiae

(13)

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Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

OREGON, ET AL.
Respondents.

On Writ of Certiorari to the United States
Court of Appeals for the Ninth Circuit

BRIEF *AMICI CURIAE* OF CHRISTIAN MEDICAL ASSOCIATION, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, UNION OF ORTHODOX JEWISH CONGREGATIONS OF AMERICA, NATIONAL ASSOCIATION OF EVANGELICALS AND CHRISTIAN LEGAL SOCIETY IN SUPPORT OF PETITIONER

Steven H. Aden *(Counsel of Record)*
Gregory S. Baylor
Kimberlee W. Colby
CENTER FOR LAW & RELIGIOUS FREEDOM
OF THE CHRISTIAN LEGAL SOCIETY
4208 Evergreen Lane, Ste. 222
Annandale, Virginia 22003
Tel.: (703) 642-1070 Ext. 3504

Counsel for Amici Curiae

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TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

INTEREST OF THE *AMICI CURIAE* AND INTRODUCTION 1

SUMMARY OF ARGUMENT 3

ARGUMENT 5

I. THE SUPREME COURT APPROPRIATELY RECOGNIZED IN *WASHINGTON V. GLUCKSBERG* THAT NO TRADITION OF STATE REGULATION OF PHYSICIAN ASSISTED SUICIDE EXISTS 5

A. The States and the Federal Government Have Historically Protected the Medical Profession from the Practice of Physician-Assisted Suicide 5

B. The Attorney General Properly Determined that Overdosing Critically Ill Patients Is Not a "Legitimate Medical Purpose" for the Use of Schedule II Controlled Substances 8

II. OREGON'S PROFESSED INTEREST IN PERMITTING THE USE OF FEDERALLY CONTROLLED SUBSTANCES TO OVERDOSE CRITICALLY ILL PATIENTS IS NOT A "STATE INTEREST" THE UNITED STATES IS BOUND TO RESPECT 11

A. Oregon Has Not Designated Schedule II Controlled Substances, Or Any Particular Medication, As the Appropriate Drug Regimen Under the Death With Dignity Act 12

B. No Accepted Standard of Medical Practice Exists Respecting the Use of Schedule II Listed Barbiturates to Overdose Critically Ill Patients 14

C. Medical Authority and Oregon's Actual Experience in Implementing the Death With Dignity Act Amply Demonstrate that Oregon Can Provide No Standard of Practice to Guide Physicians on Medical Assessment or Supervision in the Use of Schedule II Listed Barbiturates to Overdose Patients 18

CONCLUSION 23

CASES

Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C. Cir. 1994) 12

Kane v. Kulongoski, 318 Ore. 593, 871 P.2d 993 (1994) 13

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) *passim*

Raich v. Gonzales, 352 F.3d 1222 (2003), *cert. granted*, 124 S.Ct. 2909 (2004) 12

Sampson v. State of Alaska, 31 P.3d 88 (Alaska 2001) 6

United States v. Moore, 423 U.S. 122 (1975) 6

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001) 11

United States v. Rutherford, 442 U.S. 544 (1979) 15, 17

Washington v. Glucksberg, 521 U.S. 702 (1997). *passim*

Vacco v. Quill, 521 U.S. 793 (1997) ..... *passim*

Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609 (1973) 16

STATUTES, REGULATIONS AND RULES

The Assisted Suicide Funding Restriction Act of 1997, 42 U.S.C. § 14401 (1997) 7

Dispensing of Controlled Substances to Assist Suicide, 66 FED. REG. 56,607 (2001) 16

Oregon Death with Dignity Act, OR. REV. STAT. §§ 127.800-127.995 (1997) ..... *passim*

ORE. ADMIN. RULES §§ 333-009-000 – 333-009-0030 (2004) ..... *passim*

21 U.S.C. § 352(j) 17

21 U.S.C. § 802(20) 19

21 U.S.C. § 821 15

21 U.S.C. § 823(f)(1) 14

21 U.S.C. § 827(c)(1)(A) 20

21 U.S.C. § 841(a)(1) 17

21 U.S.C. § 871(b) 15

21 U.S.C. § 903 15

42 U.S.C. § 1320a-7 20

21 C.F.R. § 314.50 16

21 C.F.R. § 314.54 17

21 CFR § 314.126 16

21 C.F.R. § 320.1 16

21 C.F.R. § 320.21 16

OTHER AUTHORITIES

Bascom, P.B., and Tolle, S.W., *Responding to Requests for Physician-assisted Suicide*. 288 JAMA 91-8 (2002) 8, 10

Brief of the American Medical Association, *et al.*, as *Amici Curiae* in Support of Petitioners, *Vacco v. Quill*, 521 U.S. 793 (1997) ..... *passim*

Brief for the National Association of Pro-Life Nurses as *Amicus Curiae* in Support of Petitioners, filed May 9, 2005, *Gonzales v. Oregon*, No. 04-623 14

Crouch, Barbara Insley, *Toxicological Issues with Drugs Used to End Life*, in Battin, Margaret and Lippman, Arthur G., DRUGS USED IN ASSISTED SUICIDE AND EUTHANASIA 211 (Binghamton, New York 1996) 21, 22

Emmanuel, E.J., *Euthanasia and Physician-Assisted Suicide: A Review of the Empirical Data from the United States*, 162 ARCHIVES OF INTERNAL MEDICINE 142, 144 (2002) 9

FDA Register of Approved Pharmaceutical Products ("Orange Book"), Appl. No. 083246 ("Nembutal"), www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm 20

Ganzini, L., and Block, S., *Physician Assisted Death: A Last Resort?*, 346 N. ENGL. J. MED. 1663 (2002) 9, 10

Ganzini, L., Johnston, W.S., McFarland, B.H., Tolle, S.W. and Lee, M.A., *Attitudes of Patients With Amyotrophic Lateral Sclerosis and their Caregivers Toward Assisted Suicide*, 339 N. ENGL. J. MED. 967-973 (1998) 9

Kimsma, Gerrit K, *Euthanasia and Euthanizing Drugs in the Netherlands*, in Battin, Margaret and Lippman, Arthur G., DRUGS USED IN ASSISTED SUICIDE AND EUTHANASIA 211(Binghamton, New York 1996) 22

Klein, A.E., *Barbiturate Poisoning*, 29 AM. JUR. PROOF OF FACTS 2d 199 (2004) 21

Moeschlin, S., Clinical *Features of Acute Barbiturate Poisoning*, in Matthew Henry (ed.), ACUTE BARBITURATE POISONING 120-25 (Amsterdam: Excerpta Medica 1971) 22

New York State Task Force, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 40 (1994) 3, 4

Ore. Dept. Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005) 10, 20, 21

Oregon Department of Human Services, "FAQs About Physician-Assisted Suicide," http://egov.oregon.gov/DHS/ph/pas/faqs.shtml (4/29/05) 13, 14

Physicians Desk Reference Electronic Library, Entry for "Nembutal" (Ovation), www.thomsonhc.com/pdrel/librarian (4/29/05) 21

S. REP. NO. 106-299, at 10 (2000) 7, 11

133 SWISS MED. WKLY. 310-317 (2003) 20

Willems, D.L., Groenewoud, J.H. and van der Wal, G., *Drugs Used in Physician-Assisted Death*, 15 DRUGS & AGING 335-40 (1999) 20

INTEREST OF *AMICI CURIAE* AND INTRODUCTION[1]

The **Christian Medical Association** ("CMA") was founded in 1931 and today represents over 16,000 members—primarily practicing physicians representing the entire range of medical specialties. These members share a common commitment to the principles of biblical faith and the integration of those principles with professional practice. Among other functions, the CMA Medical Ethics Commission coordinates member experts in the field of medical ethics who formulate positions on vital issues. These positions are subsequently voted upon for adoption, amendment, or rejection by over 100 elected representatives to the national convention of the Association. CMA members and their patients will be adversely affected by the use of federally controlled medications to assist suicide, a practice diametrically opposed to traditional and current medical ethical standards.

American Association of Pro Life Obstetricians and Gynecologists ("AAPLOG") is a national organization of over 2,500 obstetricians and gynecologists who reaffirm the unique value and dignity of individual human life in all stages of growth and development from conception onward.

The **Union of Orthodox Jewish Congregations of America** (the "U.O.J.C.A.") is a non-profit synagogue

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[1] *Amici Curiae* file this brief by consent of the parties, and copies of the letters of consent are on file with the Clerk of the Court. Counsel for *Amici* authored this brief in its entirety. No person or entity, other than the *Amici*, their supporters, or their counsel, has made a monetary contribution to the preparation or submission of this brief.

umbrella organization for nearly 1,000 Jewish congregations throughout the United States. It is the largest Orthodox Jewish umbrella organization in this nation. Through its Institute for Public Affairs, the U.O.J.C.A. researches and advocates the legal and public policy positions promoted by the mainstream Orthodox Jewish community. The U.O.J.C.A. has filed briefs in federal and state courts throughout the nation in cases that affect the interests of the Jewish community and American society at large.

The U.O.J.C.A. has been concerned and active with regard to the legality of physician assisted suicide. The U.O.J.C.A. filed an *amicus* brief with this Court the last time the issue was considered in *Vacco v. Quill*, 521 U.S. 793 (1997) and *Washington v. Glucksberg*, 521 U.S. 702 (1997). The U.O.J.C.A. has also worked on this matter in the federal and state legislative arenas.

The **National Association of Evangelicals** ("NAE") is a nonprofit association of evangelical Christian denominations, local churches, organizations, institutions, and individuals that includes more than 50,000 local churches from 51 denominations, as well as over 250 other religious ministries. NAE serves a constituency of over 20 million people. The Association believes that religious freedom is a gift of God and vital to the limited government which is our American constitutional republic.

The **Christian Legal Society** ("CLS"), founded in 1961, is a nonprofit interdenominational association of Christian attorneys, law students, judges, and law professors with chapters in nearly every state and most law schools. Since 1975, the Society's legal advocacy and information division, the Center for Law and Religious Freedom, has worked for the

protection of religious belief and practice, including health care providers' rights of conscience.

SUMMARY OF ARGUMENT

In *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997), the United States Supreme Court affirmed that protection of the medical profession's integrity and ethics is a legitimate state interest justifying a governmental ban on physician-assisted suicide. Agreeing with the American Medical Association ("AMA"), the Supreme Court stressed that "physician-assisted suicide is fundamentally incompatible with the physician's role as healer." 521 U.S. at 731. Given the Court's rationale in *Glucksberg*, the Attorney General has taken an eminently reasonable position that facilitating suicide by overdose is not a legitimate medical purpose for which federally controlled substances may be used. The government's position is rationally related to several important state interests, including: safeguarding the integrity and ethics of the medical profession (*id.*); protecting persons who are depressed or mentally ill from self-destructive impulses (*id.* at 730-31); and deterring physicians from practicing voluntary and involuntary euthanasia (*id.* at 732-735).

The proponents of physician-assisted suicide advance as a primary "legitimate medical purpose" for the practice that assisted suicide is necessary to treat terminally ill persons' pain. As a factual matter, this emotionally charged argument is fundamentally flawed. First, effective, non-lethal pain treatments for critically ill patients are available. According to leading medical authorities, including the AMA, terminally ill patients' pain can be controlled without resort to suicide. *See* Brief of the American Medical Association, *et al.*, as *Amici Curiae* in Support of Petitioners (herein "AMA Brief"), at 6, *Vacco v. Quill*, 521 U.S. 793 (1997); New York State Task

Force, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 40 (1994). And, indeed, most persons seeking physician-assisted suicide do so for reasons other than pain control. AMA Brief, *supra*, at 6-7. Given that effective pain treatments exist, physician-assisted suicide serves no legitimate medical purpose. Second, under the Oregon Death with Dignity Act, OR. REV. STAT. §§ 127.800-127.995 (1997), physician-assisted suicide is *not* limited to persons whose pain is untreatable.

Oregon's professed interest in permitting the use of federally controlled medications to overdose critically ill patients is not a "state interest" the United States is bound to respect. First, the State has foresworn any "interest" in regulating the practice of assisting suicide by pharmaceutical means, as it does not purport to impose any standard of practice with regard to the type of medications used or the protocol for their administration. Second, Oregon can point to no accepted standard of medical practice respecting the use of federally listed barbiturates to overdose critically ill patients. Absent such a standard, the Attorney General cannot fulfill his statutory responsibility to ensure that Oregon physicians have not traversed "the accepted limits" of professional care as they prescribe listed medications for use pursuant to the Death With Dignity Act. Finally, in view of the notoriously unpredictable toxicology of barbiturates, the risk of complications in overdosing and the increased suffering of patients whose "lethal" doses turn out to be less than effective for the intended purpose, the Attorney General is not obligated to permit the use of listed barbiturates for the purpose of overdosing critically ill patients.

ARGUMENT

I. THE SUPREME COURT APPROPRIATELY RECOGNIZED IN *WASHINGTON V. GLUCKSBERG* THAT NO TRADITION OF STATE REGULATION OF PHYSICIAN ASSISTED SUICIDE EXISTS.

A. The States and the Federal Government Have Historically Protected the Medical Profession from the Practice of Physician-Assisted Suicide.

In its solid rejection of physician-assisted suicide as a fundamental right, the Supreme Court highlighted several state interests, each of which provided an independent legitimate state interest rationally related to a governmental ban on physician-assisted suicide. *Washington v. Glucksberg*, 521 U.S. 702, 728-35 (1997). The Supreme Court deemed each of these state interests "unquestionably important and legitimate" (*id.* at 735): 1) preserving human life (*id.* at 728-29); 2) preventing the serious public health problem of suicide, particularly protecting persons suffering from depression, mental illness, or untreated pain from suicide (*id.* at 729-31); 3) "protecting the integrity and ethics of the medical profession" (*id.* at 731); 4) "protecting vulnerable groups—including the poor, the elderly, and disabled persons—from abuse, neglect, and mistakes" (*id.* at 731-32); and 5) avoiding "the path to voluntary and perhaps even involuntary euthanasia" (*id.* at 732-35).

Of particular importance to *Amici*, the Supreme Court agreed with the American Medical Association ("AMA") that "physician-assisted suicide is fundamentally incompatible with the physician's role as healer." *Id.* at 731, *quoting*, AMA Code of Ethics § 2.211 (1994). In its brief to the Court in *Vacco v. Quill*, the AMA explained:

> The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides both medicine and nursing. It is a power that most physicians and nurses do not want and could not control.

Brief of the American Medical Association, *et al.*, as *Amici Curiae* in Support of Petitioners (hereinafter "AMA Brief"), at 2, *Vacco v. Quill*, 521 U.S. 793 (1997). The Court affirmed that the protection of the integrity and ethics of the medical profession is a legitimate state interest justifying a governmental ban on physician-assisted suicide. *Glucksberg*, 521 U.S. at 731. *See also Sampson v. State of Alaska*, 31 P.3d 88, 97 (Alaska 2001) (ban on assisted suicide "furthers the state's protective interests by promoting the integrity of the medical profession and fostering healthy physician-patient relationships"). The Court noted that the AMA's Council on Ethical and Judicial Affairs had concluded that the "'societal risks of involving physicians in medical interventions to cause patients' deaths is too great.'" 521 U.S. at 731, *quoting* Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992). The AMA warned the Supreme Court that "[t]he ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics." AMA Brief, *supra*, at 5.

It would seem self-evident that the intentional infliction of death ought not to be considered an acceptable method of pain treatment, for, as this Court has observed, "In almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide." *Glucksberg*, 521 U.S. at 710. *See id.* at 723 ("[w]e are confronted with a consistent and almost universal tradition that has long rejected the asserted right, and continues explicitly to reject it today, even for terminally ill, mentally competent adults"). Laws against physician-assisted

suicide are "longstanding expressions of the States' commitment to the protection and preservation of all human life." *Id.*

Federal law reflects the national government's commitment to protecting the medical profession against physician-assisted suicide. The Assisted Suicide Funding Restriction Act of 1997, 42 U.S.C. § 14401 (1997), "prohibits the use of Federal funds to cause a patient's death, effectively prohibits the practice of assisted suicide in Federal health facilities, removes it from the scope of 'rights' under State laws of which patients must be informed under the Federal Patient Self-Determination Act, and forbids Federal subsidies to health programs or benefit packages which include assisted suicide." S. REP. NO. 106-299, "The Pain Relief Promotion Act,"at 10 (2000) (hereinafter "S. Rep. No. 106-299"). The Assisted Suicide Funding Restriction Act passed the House of Representatives, 398-16, and the Senate, 99-0. *Id.* Upon signing it, President Clinton said it "will allow the Federal Government to speak with a clear voice in opposing these practices," and "to endorse assisted suicide would set us on a disturbing and perhaps dangerous path." *Id.* at 11.

In light of this longstanding tradition of rejection of physician assisted suicide by the medical profession and both the federal government and the governments of the several States, *Amici* submit that the burden rests with Oregon to demonstrate that it has endeavored to establish assisted suicide as a medically accepted practice and has adopted professional standards to regulate the dispensing of medications for that purpose to guide the Attorney General in determining whether federally listed medications are used for "legitimate medical purposes" under the Controlled Substances Act. Oregon simply cannot meet that burden.

B. The Attorney General Properly Determined that Overdosing Critically Ill Patients Is Not a "Legitimate Medical Purpose" for the Use of Schedule II Controlled Substances.

Thrown against the self-evident proposition that medical overdosing of patients is not an appropriate form of patient care is the mistaken belief that terminally ill persons endure untreatable, unbearable pain and, therefore, should be allowed to be prescribed medications to kill themselves. But these fears are medically unsupported because effective pain treatment does exist. AMA Brief, *supra*, at 6. In fact, as the Court recognized in *Glucksberg*, "'intolerable physical symptoms are not the reason most patients request physician-assisted suicide or euthanasia.'" *Glucksberg*, 521 U.S. at 730, *quoting* Back, *et al.*, *Physician-Assisted Suicide and Euthanasia in Washington State*, 275 JAMA 919, 924 (1996). The AMA informed the Court in *Vacco* "that the demand for physician-assisted suicide does not come principally from those seeking relief from physical pain." AMA Brief, *supra*, at 6-7, *citing* Ezekiel J. Emanuel, *et al.*, *Euthanasia and Physician-Assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 LANCET 1805, 1809 & nn.6, 12 (1996). Instead, according to the AMA, "[m]ost patients that request suicide do so out of concerns that, *in the future*, their pain may become intolerable, they may suffer a loss of dignity and become dependent upon others, or they will excessively burden their families." AMA Brief, *supra*, at 8, 14-15 (emphasis added). Many persons requesting physician-assisted suicide subsequently withdraw their request if their depression or fears are treated. *Glucksberg*, at 730.

Researchers Paul Bascom and Susan Tolle noted recently in an article in the Journal of the American Medical Association, "Physical pain may cause severe distress, but it *is the*

impending disintegration of the person, loss of control, and unresolved spiritual or psychological issues that may cause the most intense suffering." Bascom, P.B., and Tolle, S.W., *Responding to Requests for Physician-assisted Suicide*, 288 JAMA 91-8 (2002) (italics added). The New England Journal of Medicine, commenting on findings regarding factors reported by Oregon sufferers of Amyotrophic Lateral Sclerosis ("ALS," or "Lou Gehrig's Disease")[2] who requested assisted suicide, stated that the studies "suggest that the loss of autonomy and control" that characterize that disease were significant factors. Ganzini, L., Johnston, W.S., McFarland, B.H., Tolle, S.W. and Lee, M.A., *Attitudes of Patients With Amyotrophic Lateral Sclerosis and their Caregivers Toward Assisted Suicide*, 339 N. ENGL. J. MED. 967-973 (1998). Far stronger even than depression in predicting an interest in assisted suicide among ALS patients is hopelessness. *Id.* According to the National Institutes of Health's Ezekiel Emmanuel, "The recent focus on end-of-life care has revealed the multiplicity of interventions, besides euthanasia and [assisted suicide], that can be used to improve the quality of life of the terminally ill. Consequently, [assisted suicide] seems less necessary and desirable to ensure good end-of-life care." Emmanuel, E.J., *Euthanasia and Physician-Assisted Suicide: A Review of the Empirical Data from the United States*, 162 ARCHIVES OF INTERNAL MEDICINE 142, 144 (2002). "If society values the dying and can ensure respectful medical

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[2] ALS is a progressive, debilitating and ultimately fatal disease that attacks the motor neuron system, causing loss of function and wasting in muscle tissue. Death ordinarily ensues within three to five years after onset. Ganzini, L., Johnston, W.S., McFarland, B.H., Tolle, S.W. and Lee, M.A., *Attitudes of Patients With Amyotrophic Lateral Sclerosis and their Caregivers Toward Assisted Suicide*, 339 N. ENGL. J. MED. 967-973 (1998). ALS patients rank among the highest reported users of assisted suicide in Oregon and elsewhere.

care for all terminally ill patients, then legalized physician-assisted death should be relevant in only a small number of cases." Ganzini, L., and Block, S., *Physician Assisted Death: A Last Resort?*, 346 N. ENGL. J. MED. 1663 (2002). This view is borne out by actual experience in Oregon: of the approximately ten percent of terminal patients who seriously consider assisted suicide, only 1 in 10 specifically request it; and only 1 in 10 of those requesting it actually take a lethal prescription. Ba[illegible]n and Tolle, *supra*.

Oregon's experience under the Death With Dignity Act has confirmed the validity of the AMA's caution that pain control is not the predominant reason for seeking physician assistance in committing suicide. Only twenty-two percent of patients who requested physician-assisted suicide in the year 2004 did so in part because of "inadequate pain control" or concerns relating to it. Ore. Dept. Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005), at 15, 24 (Table 4) (hereinafter "Oregon Report 2004"). Instead, the leading "end of life concerns" reported were "losing autonomy" and "decreasing ability to participate in activities that make life enjoyable." *Id.* Moreover, despite this well-documented understanding in the medical community, Oregon has utterly failed to ensure that potentially suicidal terminal patients are being provided with necessary mental health care. In the last year, only 5% of assisted suicide patients received psychiatric evaluation, and the level has declined dramatically since the Act became operative in 1998, from 31% in that first year. *See id.*, at 13.

Further, by its explicit language, the Death With Dignity Act assumes that persons for whom pain control is feasible may nonetheless receive physician assistance in committing suicide. The Act states that "a qualified patient" may "request and obtain a prescription to end his or her life… after being fully

informed by the attending physician of… the feasible alternatives, including … pain control." ORE. REV. STATS. § 127.800(7)(e). *See also* ORE. REV. STATS § 127.815(1)(c)(E)("[t]he attending physician shall… [i]nform the patient of… [t]he feasible alternatives, including… pain control); § 127.897 (the statutory "Form of the Request" requires the patient to affirm that he or she has been "fully informed of… the feasible alternatives, including… pain control"). *See* S. REP. NO. 106-299, *supra*, at 27, *citing* Amy Sullivan, *et al., Legalized Physician-Assisted Suicide in Oregon—The Second Year*, 342 NEW ENG. J. MED. 598 (2000).

Given that most patients who seek aid in dying in Oregon and elsewhere do not do so because of complaints of ineffective pain management, and for those who do, effective pain treatments exist, and in view of the fact that spiritual and psychological factors such as the loss of enjoyment of life and loss of autonomy are the overriding reasons patients seek aid in dying, physician-assisted suicide cannot be said to serve any legitimate medical purpose. *See, e.g.*, S. REP. NO. 106-299, at 6 (bill "finds that the dispensing and distribution of controlled substances…are not legitimate medical purposes when used to assist in a suicide or euthanasia").

II. OREGON'S PROFESSED INTEREST IN PERMITTING THE USE OF FEDERALLY CONTROLLED SUBSTANCES TO OVERDOSE CRITICALLY ILL PATIENTS IS NOT A "STATE INTEREST" THE UNITED STATES IS BOUND TO RESPECT.

A proper respect for Federalism does not obligate the Attorney General to defer to State majoritarian judgments on the practice of medicine within their borders. *See generally United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001)(Attorney General was not obligated to

recognize a "medical necessity" exception to prohibition on use of cannabis pursuant to Controlled Substances Act ("CSA") despite California law authorizing medicinal use of cannabis); *United States v. Rutherford*, 442 U.S. 544, 554, n. 10 (1979)(Food and Drug Administration was not obligated to recognize express or implied exemption from requirement of demonstrating safety and efficacy of Laetrile for treatment of terminal cancer despite its legalization for such purpose by seventeen states); *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994)(Attorney General was not obligated to re-list cannabis from Schedule I to Schedule II under the Controlled Substances Act); *but cf. Raich v. Gonzales*, 352 F.3d 1222 (2003), *cert. granted*, 124 S.Ct. 2909 (2004) (holding that Commerce Clause authority does not extend to regulating intrastate noncommercial cultivation of cannabis for personal medical purposes as recommended by a patient's physician under California law). Even if deference were appropriate, the State of Oregon's professed interest in allowing its physicians to use federally controlled substances to overdose critically ill patients pursuant to the Death With Dignity Act is not a "state interest" in the regulation of medicine that the federal government is bound to respect.

A. Oregon Has Not Designated Schedule II Controlled Substances, Or Any Particular Medication, As the Appropriate Drug Regimen Under the Death With Dignity Act.

The State of Oregon asserts that its Death With Dignity Act contemplates the use of Schedule II controlled substances to allow terminally ill patients to end their own lives.[3] In fact,

[3] "The [Act] establishes tightly controlled procedures under which competent, terminally-ill adults who are under the care of an attending physician may obtain a prescription for Schedule II

neither Measure 16, the Oregon ballot initiative that inaugurated the Death With Dignity Act, nor the regulations promulgated by the Oregon Department of Health to administer the Act specifies which therapeutic protocol is to be employed by a physician. *See* ORE. STATS. § 127.800 through 127.995 (type of lethal medication unspecified); ORE. ADMIN. RULES, §§ 333-009-000 – 333-009-0030 (2004) (same). The ballot for Measure 16, which included the entire text of the proposed Act, likewise failed to specify what substances would be used for the prescription, and the measure simply referred to a prescription for "lethal drugs" without further explication. *See Kane v. Kulongoski*, 318 Ore. 593, 600, 871 P.2d 993, 997 (1994)(reviewing proposed language of Measure 16 ballot caption). Consequently, the Act cannot reasonably be viewed as an authoritative pronouncement by the citizens of Oregon on the propriety of employing Schedule II medications for the termination of life.

Moreover, Oregon's position that the Death With Dignity Act constituted "a State's decision about *specific medical uses of controlled substances* that admittedly have approved medical uses" (Brief in Opposition at 9) (emphasis added) is belied by the fact that the State does not purport to designate either the particular medication to be used for a Death With Dignity Act prescription or the proper protocol for its administration. Rather, the State has made it clear to its citizens that it affirmatively disavows any participation in that decision, instead leaving the matter to the discretion of individual physicians. *See* Oregon Department of Human Services, "FAQs About Physician-Assisted Suicide," http://egov.oregon.gov/DHS/ ph/pas/faqs.shtml (posted as of

controlled substances in sufficient kind and quantity to allow them to control the time, place and manner of their own impending death." Brief for Respondent in Opposition, at 1.

April 29, 2005).[4] To assert that Oregon has allowed by statute and regulation state-licensed physicians to assist in suicide without fearing legal consequences is not the same as demonstrating that the practice is, or even can be, conducted in accordance with generally accepted standards of practice within the profession. *See generally* Brief for the National Association of Pro-Life Nurses as *Amicus Curiae* in Support of Petitioners, filed May 9, 2005, *Gonzales v. Oregon*, No. 04-623 (explaining distinction between Oregon law and accepted medical practices). In view of the fact that Oregon's health department has washed its hands of the medically crucial decision of what substances, federally controlled or otherwise, should be used to overdose critically ill patients, it simply cannot be said that any "recommendation of the appropriate State licensing board or professional disciplinary authority" has been made under the CSA. *See* 21 U.S.C. § 823(f)(1).

B. No Accepted Standard of Medical Practice Exists Respecting the Use of Schedule II Listed Barbiturates to Overdose Critically Ill Patients.

It is undoubtedly true, as Justice O'Connor observed in *Glucksberg*, that "the ... challenging task of crafting appropriate procedures for safeguarding ... liberty interests is entrusted to the 'laboratory' of the States... in the first instance." 521 U.S. at 737 (O'Connor, J., concurring); *Oregon v. Ashcroft*, 368 F.3d 1118, at 1124 (9th Cir. 2004) (quoting

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[4] Q. What kind of prescription will a patient receive?

A. *It is up to the physician to determine the prescription.* To date, most patients have received a prescription for an oral dosage of a barbiturate.

Id. (emphasis added).

same). However, Oregon's assertion, accepted by the court of appeals, that the Attorney General's Directive contravened the principle of federalism that "state lawmakers... are the primary regulators of professional [medical] conduct," *see* 368 F.3d at 1124 (quoting *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002), is an argument that chases its own tail. While it is a truism that "direct control of medical practice in the states is beyond the power of the federal government," 368 F.3d at 1124, quoting *Linder v. United States*, 268 U.S. 5, 18 (1925), Respondent cannot gainsay that authority over the standards for dispensing federally controlled medications has been conferred on the Attorney General by the States via Congress' enactment of the Controlled Substances Act ("CSA"). The Court in *United States v. Moore*, 423 U.S. 122 (1975), interpreted this grant of authority under the CSA to "require" the federal government "to determine the appropriate methods of professional practice." 423 U.S. at 144, quoting 42 U.S.C. § 290bb-2a.

As the Court of Appeals recognized, the CSA prohibits practitioners from prescribing controlled substances except for a "legitimate medical purpose" and "in the usual course of professional treatment." 368 F.3d at 1122, quoting 21 C.F.R. § 1306.04. Congress granted to the Attorney General broad authority to promulgate "rules and regulations... relating to the registration and control of the... dispensing of controlled substances," 21 U.S.C. § 821, and "any rules, regulations, and procedures by which he may deem necessary and appropriate for the efficient execution of his functions." 21 U.S.C. § 871(b). To the extent a State's laws irreconcilably conflict with the CSA and its regulations, they are preempted. 21 U.S.C. § 903. The Ashcroft Directive is well within the Attorney General's authority to provide cautionary guidance to DEA-registered practitioners regarding dispensing practices that are so removed from the medical standard that they may

subject practitioners to sanctions, including potential loss of their license. *Dispensing of Controlled Substances to Assist Suicide*, 66 FED. REG. 56,607 (2001). In the case of lethal medications prescribed pursuant to the Death With Dignity Act, the Attorney General has appropriately made the determination that the use of controlled substances exceeds the bounds of accepted standards.

Of course, there is no federally-approved drug for which the primary indication is the cessation of mental or physical suffering by the termination of life. Nor could there be, since the Food and Drug Act and its implementing regulations require, among other things, that both "safety" and "efficacy" of a drug for its intended purpose (its "indication") be demonstrated in order to approve the drug for distribution and marketing to the public. *See generally Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 617-21 (1973) and companion cases cited therein (discussing "safety and efficacy" regulations); *see, e.g.*, 21 C.F.R. § 314.50 (new drug application requires controlled clinical studies and showing of safety and effectiveness of product). Safety and effectiveness must be demonstrated by adequate and well-controlled studies, 21 CFR § 314.126(a), and uncontrolled or partially controlled studies are unacceptable as the sole basis to prove effectiveness. 21 C.F.R. § 314.126(e). Proof of bioequivalence (the absence of significant differences in the rate and extent to which the active ingredient becomes available when administered at the same dosages – *see* 21 C.F.R. § 320.1(e)) and bioavailability (the rate and extent to which the active ingredient is absorbed from the drug product – *see* 21 C.F.R. § 320.1(a)), are also required. *See* 21 C.F.R. § 320.21. The standards for the approval of a new indication for an existing drug (such as the barbiturates used in for assisted suicide overdoses, the primary indications of which are to produce sedation and to induce sleep), likewise mandate a

showing of proof of efficacy by two randomized and controlled trials. *See* 21 C.F.R. § 314.54 (procedure for a new indication should be supported by information as needed to support the safety and effectiveness of the drug product). The federal government regards a drugs as "misbranded" if it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

United States v. Moore, supra, held that the United States may prosecute a physician who dispenses controlled substances outside the "accepted limits" of medical practice. The defendant in *Moore* was charged with the knowing and unlawful distribution and dispensation of methadone, a Schedule II controlled substance, in violation of 21 U.S.C. § 841(a)(1). 423 U.S. at 124. The Court noted that he was shown to have been prescribing controlled substances with "little or no medical assessment or supervision" in furtherance of an alleged radical and controversial treatment for heroin addicts. *Moore*, at 127. Here, as in *Moore*, there are no guidelines or standards acceptable to the medical profession, either nationally or in Oregon, to guide the Attorney General in making determinations in individual cases regarding the safety and efficacy of using depressive narcotics to terminate life in what amounts to a highly risky and controversial State experiment in medical treatment.

It is understandable, then, that the State of Oregon does not purport to impose or even recognize any standard of practice for physicians with respect to the appropriate drug regimen for terminating critically ill patients. The Court's *Amici* believe it is legitimate under these circumstances for the Court to wonder how the State of Oregon can insist that the Federal government is bound to respect its views on what constitutes "legitimate medical practice" when Oregon itself recognizes no medical

standards for the "practice" of dispensing massive overdoses of lethal medications.

C. Medical Authority and Oregon's Actual Experience in Implementing the Death With Dignity Act Amply Demonstrate that Oregon Can Provide No Standard of Practice to Guide Physicians on Medical Assessment or Supervision in the Use of Schedule II Listed Barbiturates to Overdose Patients.

The appeals court rather disingenuously insisted that it took "no position on the merits or morality of physician assisted suicide." *Oregon v. Ashcroft*, 368 F.3d at 1123. Essentially opining on several highly disputed medical issues, the two-member panel majority effused, "[I]t is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives," *id.* at 1123, n. 5. These controversial medical issues include whether a massive overdose of barbiturates is a relatively "reliable" means of terminating life and whether death by such an overdose is "painless." Medical authority and Oregon's own ten-year experience under the Death With Dignity Act suggest the contrary.

Amici initially note that complicating Oregon's argument that only patients in "end-of-life care" are eligible to receive lethal prescriptions under the Act is the fact that it is not always medically possible to predict the course of serious diseases, as the Court recognized in *United States v. Rutherford*, 442 U.S. 544 (1979). Rejecting the notion that the "safety and efficacy" requirements of the Food, Drug and Cosmetic Act were inapplicable to the prescribing of laetrile for "terminal" cancer patients, the Court observed:

> The FDA's practice [of considering "effectiveness" of drugs used to treat terminal patients] also reflects the recognition, amply supported by expert medical testimony in this case, that with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect. Cancers vary considerably in behavior and in responsiveness to different forms of therapy. Even critically ill individuals may have unexpected remission and may respond to conventional treatment.

Id. at 556-57; *see also id.*, n. 14, quoting 42 FED.REG. 39768, 39805 (1977) (Statement of Dr. Peter Wiernik, Chief of the Clinical Oncology Branch of the National Cancer Institute's Baltimore Research Center) ("[N]o one can prospectively define the term 'terminal' with any accuracy.... Many patients who are critically ill respond to modern day management of cancer"). If no generally accepted standard exists for determining "terminal" status for purposes of eligibility for a prescription overdose under the Act, Oregon's participating physicians may operate an unaccountable regime of dispensing lethal doses to patients who might otherwise have been provided life-prolonging medical care.

Nor are standards available to guide the Attorney General in reviewing whether assisted suicide is the "best" or "most reliable" means for a physician to assist a patient in ending his or her life. Federal law mandates that the Attorney General be able to determine whether a DEA-registered physician has prescribed medications in accordance with the usual course of professional practice. *See, e.g.*, 21 U.S.C. § 802(20)(a "practitioner" is one who is "registered ... by the United States or the jurisdiction in which he practices ... to distribute [or] dispense ... .a controlled substance *in the course of professional practice*...") (emphasis added); 21 U.S.C. §

827(c)(1)(A)(record and reporting requirements of § 827 are inapplicable to narcotic drugs in Schedules II through V when prescribed "by a practitioner *in the lawful course of his professional practice*")(emphasis added); 42 U.S.C. § 1320a-7(a) and (b)(6) (authorizing the Secretary to exclude from "any Federal health care program" a physician who furnishes services "*substantially in excess of the needs of ... patients*")(emphasis added). In the case of lethal medications prescribed pursuant to the Death With Dignity Act, the Attorney General would be utterly unable to do so.

According to statistics kept pursuant to the Act by the Oregon Department of Human Services, the fast-acting barbiturate Pentobarbital is the drug of choice for assisted suicide, used in approximately two-thirds of cases. *Oregon Report 2004*, at 5; *see also* Willems, D.L., Groenewoud, J.H. and van der Wal, G., *Drugs Used in Physician-Assisted Death*, 15 DRUGS & AGING 335-40 (1999) ("Recent research, mainly from the Netherlands, has shown that high doses of barbiturates are usually effective for physician-assisted suicide."); 133 SWISS MED. WKLY. 310-317 (2003) (a barbiturate was the only drug used in 300 of 331 physician assisted suicide deaths). However, use of Pentobarbital for this purpose is problematic, since the drug is available solely in liquid injectable format. *Cf.* FDA Register of Approved Pharmaceutical Products ("Orange Book"), Appl. No. 083246 ("Nembutal"), www.accessdata.fda.gov/scripts/ cder/ob/docs/tempai.cfm (for active ingredient "pentobarbital" in "OB_Rx" database table in "Active" status showing liquid injectable form); *and id.* (search results for "pentobarbital" in same table in "Inactive" status showing numerous oral capsule and tablet forms) (posted May 5, 2005). Since most patients are unable to inject themselves, an oral solution must be formulated. There is, naturally, no pharmacokinetic data to guide the dosing for such a procedure, nor any accepted standards for concocting an oral suspension

from an injectable solution of barbiturates.

It is highly doubtful that a generally accepted protocol for lethally overdosing patients could even be developed to guide the Attorney General in determining the standard of practice for the use of controlled substances to assist suicide, given the known toxicological unpredictability of barbiturates. Barbiturates are central nervous system depressants and produce drowsiness, sedation and hypnosis. Physicians Desk Reference Electronic Library, Entry for "Nembutal" (Ovation), www.thomsonhc.com/pdrel/librarian (4/29/05). "It is difficult to predict how much of any barbiturate will be a fatal dose for any given person." Klein, A.E., *Barbiturate Poisoning*, 29 AM. JUR. PROOF OF FACTS 2d 199, § 7. While a lethal dose is generally taken to be approximately ten times the therapeutic dose, "fatal doses and various blood and tissue levels have been found to vary considerably from one individual to another." *Id.*, § 6. The requisite dosage to induce fatality depends on numerous factors, including 1) which drug or combination of drugs was ingested; 2) whether alcohol was consumed with the drug; 3) how quickly the drug is absorbed in the system; and 4) any tolerance the user may have developed. *Id.* Fatal blood drug levels vary widely for a single drug, indicating that some are able to tolerate much larger doses than others. *Id.*, § 6; *see also id.*, § 7 (discussing factors in varying degrees of tolerance among non-abusers). Moreover, a risk of vomiting accompanies barbiturate medications, rendering the lethality of the dose (and hence the "effectiveness") questionable. Oregon reported three patients who experienced vomiting complications in 2004, a complication rate of 8%. *See* Oregon Report 2004, at 24, Table 4. Reduced effectiveness or complications in taking prescribed overdoses may prolong the dying process and considerably increase patient suffering. One researcher observes:

> Terminally ill patients who are considering ingesting drugs to hasten death and persons forming opinions on such acts should understand that many factors may affect the toxicity of various drugs and chemicals used to end life and that published euthanizing recipes may be unreliable and lead to prolonged suffering.

Crouch Barbara Insley, *Toxicological Issues with Drugs Used to End Life*, in Battin, Margaret and Lippman, Arthur G., DRUGS USED IN ASSISTED SUICIDE AND EUTHANASIA 211 (Binghamton, New York 1996).

Sequelae from "ineffective" assisted suicide dosing may include gross muscle necrosis from the pooling of blood, blistering of the hands and feet, toxic psychosis, pulmonary edema with agonal respiration, and lung abscesses. Moeschlin, S., *Clinical Features of Acute Barbiturate Poisoning*, in Matthew Henry (ed.), ACUTE BARBITURATE POISONING 120-25 (Amsterdam: Excerpta Medica 1971). Because of the undesirability of these potential complications, the Dutch protocol contemplates the administration of additional drugs to ensure death when patients take voluntary doses of drugs orally:

> The use of oral agents can be effective. If oral agents are used, physicians need to be aware of the possibility that *active termination using a muscle relaxant may be necessary*.

Kimsma, Gerrit K, *Euthanasia and Euthanizing Drugs in the Netherlands*, in Battin and Lippman, *supra*, at 197-203 (emphasis added). Clearly, where neither the State or Oregon nor its medical profession can point to reliable standards to be utilized to guide physicians who seek to "effectively" overdose their patients, the Attorney General was well within his

discretion to advise that dispensing federally listed substances for the purpose is not a "legitimate medical practice."

CONCLUSION

For the reasons set forth herein, the Court's *Amici* respectfully submit that the decision of the Ninth Circuit Court of Appeals should be reversed and the case remanded to the District Court with instructions to enter judgment for the Petitioner.

Respectfully submitted,

Steven H. Aden
Counsel of Record
Gregory S. Baylor
Kimberlee W. Colby
CHRISTIAN LEGAL SOCIETY
CENTER FOR LAW &
RELIGIOUS FREEDOM
4208 Evergreen Lane, Ste. 222
Annandale, Virginia 22003
Tel.: (703) 642-1070

Counsel for Amici Curiae

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In The
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ALBERTO R. GONZALES, in his official capacity as United States Attorney General, et al.,

Petitioners,

v.

State of OREGON, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

AMICUS CURIAE BRIEF OF SENATORS RICK SANTORUM, TOM COBURN, M.D., JAMES M. INHOFE, JIM DEMINT, CHRISTOPHER S. BOND, LARRY CRAIG, JUDD GREGG, AND SAM BROWNBACK, AND REPRESENTATIVES STEVE CHABOT, CHRIS SMITH, JACK KINGSTON, JOHN SHIMKUS, JOSEPH R. PITTS, HENRY HYDE, MARK GREEN, TODD AKIN, ROSCOE BARTLETT, JEFF MILLER, STEVE KING, THOMAS PETRI, MARK E. SOUDER, PETE KING, PAUL RYAN, VIRGIL H. GOODE, JR., GENE TAYLOR, JOHN N. HOSTETTLER, AND RALPH HALL IN SUPPORT OF PETITIONERS

Counsel for Amici
DONALD A. DAUGHERTY, JR.*
JOHN B. TUFFNELL
WHYTE HIRSCHBOECK DUDEK S.C.
555 E. Wells Street, Suite 1900
Milwaukee, WI 53202
(414) 273-2100

**Counsel of Record for Amici*

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
INTEREST OF AMICI CURIAE	1
SUMMARY OF ARGUMENT	2
ARGUMENT	3
I. A REVIEW OF THE LEGISLATIVE HISTORY IS INSTRUCTIVE FOR DISCERNING CONGRESSIONAL INTENT BEHIND THE CSA	5
II. THE CSA'S LEGISLATIVE HISTORY CLEARLY SHOWS THAT CONGRESS INTENDED THE FEDERAL GOVERNMENT TO PLAY AN ACTIVE ROLE IN REGULATING THE PRESCRIPTION AND DISPENSING OF CONTROLLED SUBSTANCES BY PHYSICIANS	6
A. The CSA Enhanced The Federal Government's Long-Standing Role As The Regulator Of Controlled Substances	6
B. The 1974 Amendments Distinguished Between The Roles Of HHS And The Attorney General With Regard To Treatment Programs For Narcotics Addicts And Are Irrelevant To The Issues Before This Court	10
C. The 1984 Amendments Clarified The Federal Government's Authority To Act Where States Ineffectively Regulated Physician Use Of Controlled Substances	12
D. The Interpretive Rule Is Based Upon A Reasonable Interpretation Of The CSA's Legislative History	16

TABLE OF CONTENTS – Continued

Page

E. The Federal Government's Role As Regulator Of Controlled Substances Does Not Displace The States' Role As Primary Regulators Of The Practice Of Medicine.... 18

III. THE ATTORNEY GENERAL HAS THE AUTHORITY TO DETERMINE WHETHER PHYSICIAN-ASSISTED SUICIDE VIOLATES THE CSA, NOTWITHSTANDING THE ABSENCE OF SPECIFIC REFERENCES TO THE PRACTICE IN THE LEGISLATIVE HISTORY..... 21

CONCLUSION..... 27

TABLE OF AUTHORITIES

Page

CASES:

Am. Pharm. Ass'n v. Weinberger, 377 F. Supp. 824 (D. D.C.1974), *aff'd*, 530 F.2d 1054 (D.C. Cir. 1976)..... 13

Babbit v. Sweet Home Chapter of Communities for a Greater Oregon, 515 U.S. 687 (1995)..... 5

Barnhart v. Walton, 535 U.S. 212 (2002)..... 5

Browder v. United States, 312 U.S. 335 (1941)..... 23, 24

Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984)..... 17

Dep't of Commerce v. United States House of Representatives, 525 U.S. 316 (1999)..... 5

Dickerson v. New Banner Institute, Inc., 460 U.S. 103 (1983)..... 5

H.J. Inc. v. Northwestern Bell Telephone Co., 492 U.S. 229 (1989)..... 22, 24

INS v. Cardoza-Fonseca, 480 U.S. 421 (1987)..... 5

Lewis v. United States, 523 U.S. 155 (1998)..... 5

Mississippi Band of Choctaw Indians v. Holyfield, 490 U.S. 30 (1989)..... 5

Nationsbank of North Carolina, N.A. v. Variable Annnuity Life Ins. Co., 513 U.S. 251 (1995)..... 17

Negonsott v. Samuels, 507 U.S. 99 (1993)..... 5

Oncale v. Sundowner Offshore Servs., Inc., 523 U.S. 75 (1998)..... 23, 24

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004), *cert. granted*, 125 S. Ct. 1299 (2005)..... *passim*

TABLE OF AUTHORITIES – Continued

Page

Rust v. Sullivan, 500 U.S. 173 (1991) 24

United States v. Moore, 423 U.S. 122 (1975) 7, 10

United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975) 7

United States v. Southwestern Cable Co., 392 U.S. 157 (1968) 23, 24

United States v. Steinberg, 525 F.2d 1126 (2d Cir. 1975) 7

United States v. Upthegrove, 504 F.2d 682 (6th Cir. 1974) 7

West v. Gibson, 527 U.S. 212 (1999) 5

STATUTES AND REGULATIONS:

21 C.F.R.:
§ 1306.04(a) 10, 16, 18
§ 1308.12(e) 8

66 Fed. Reg. 56,607 (Nov. 9, 2001) 2, 10, 18

Pub. L. No. 91-513, § 202, 84 Stat. 1236 8

Pub. L. No. 91-518, § 201(a)(1), 84 Stat. 1236 (1 U.S.C. § 802(5) 8

Pub. L. No. 98-473, Title II § 501 (1984), 98 Stat. 2068 15

Assist Suicide Funding Restriction Act, Pub. L. 105-12 (1997) 25

Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 100 (amended 1984), *reprinted in* 1970 U.S.C.C.A.N. 4566 ..... *passim*

TABLE OF AUTHORITIES – Continued

Page

Controlled Substances Act:
21 U.S.C. § 801, *et seq.* 1

Death With Dignity Act, Or. Rev. Stat. § 127.800, *et seq.* (2003) 2

Drug-Induced Rape Prevention and Punishment Act of 1996, Pub. L. No. 104-305, § 1 12

Harrison Act of 1914, ch.1 (codified as amended at 21 U.S.C. § 801, *et seq.*) 6, 7

Methamphetamine Anti-Proliferation Act of 2000, Pub. L. No. 106-310, Div. B., Title XXXVI, § 3601 12

Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 ..... 10, 12

MISCELLANEOUS:

116 Cong. Rec. 977 (Comments of Sen. Dodd, Jan. 23, 1970) 22

116 Cong. Rec. 18913 (1970) (Sen. McClellan) 22

130 Cong. Rec. H9679 (daily ed. Sept. 18, 1984) 14

130 Cong. Rec. H9680 (daily ed. Sept. 18, 1984) 14

130 Cong. Rec. H9742 (daily ed. Sept. 18, 1984) 15

130 Cong. Rec. S733 (daily ed. Feb 2, 1984) 15

130 Cong. Rec. S758 (daily ed. Feb. 2, 1984) 15

130 Cong. Rec. S9681-82 (daily ed. Feb. 2, 1984) 17

H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566 ..... 7, 8, 9, 19, 26

H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029 11

TABLE OF AUTHORITIES – Continued

Page

H.R. Rep. No. 98-1030 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182 ..... 13, 19, 20

S. Rep. No. 98-225 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182 4

American Medical Association, *Code of Medical Ethics* § 2.211 (2005) 25

American Medical Association, Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229 (1992) 26

American Nursing Association, Position Statement (*available at*: http://nursingworld.org/readroom/position/ethics/etsuic.htm) 26

Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 403-04 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration) 14

Editorial, *Deadly Milestone: 5 years of assisted suicide*, amednews.com, April 21, 2003 (*available at*: http://www.ama-assn.org/amednews/2003/04/21/edsb0421.htm) 26

Health & Human Servs., *Medicare Benefit Policy Manual, chs. 16 & 20* (*available at*: http://www.cms.hhs.gov/manuals/102_policy/bp102c16.pdf) 25

Hugh I. Schade, M.D., Denial of Application, 60 Fed. Reg. 56,354 (Nov. 8, 1995) 24

Jonathan Erlen & Joseph F. Spillane, *Federal Drug Control: The Evolution of Policy and Practice* (2004) 6

TABLE OF AUTHORITIES – Continued

Page

Letter from Hon. Janet Reno, Attorney General of the United States, to Hon. Henry Hyde, Chairman, Committee on the Judiciary United States House of Representatives (June 5, 1998) 11

Letter from Hon. Thomas A. Constantine, Administrator of the Drug Enforcement Administration of the United States to Hon. Henry J. Hyde, Committee on the Judiciary, United States House of Representatives (Nov. 5, 1997) 24

Memorandum from Deputy Assistant Attorney General Sheldon Bradshaw to Hon. John Ashcroft, "Whether a Physician-Assisted Suicide Serves a 'Legitimate Medical Purpose' Under The Drug Enforcement Administration Regulations Implementing the Control Substances Act" (June 27, 2001) 18, 20

Oregon Dep't of Human Servs., Off. Of Disease Prevention and Epidemiology, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005) (*available at*: http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf) 8

Press Release, Oregon Dep't of Human Servs., Oregon Public Health Servs., *Fewer Oregonians Used Death With Dignity Act in 2001* (Feb. 6, 2002) (*available at*: http://www.ohd.hr.state.or.us/news/2002/0206pas.htm) 8

Task Force on the Nurse's Role in End-of-Life Decisions, Center for Ethics and Human Rights (1994) 26

INTEREST OF AMICI CURIAE[1]

Amici curiae have the honor of serving in the United States Congress. Amici Craig, Gregg, Hyde, Smith, Petri and Hall served in Congress at the time of the 1984 amendments to the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, *et seq.* In addition, several of the amici have served or are currently serving on relevant committees of the Senate and House of Representatives, including Congress' Judiciary Committees, the Senate Committee on Health, Education, Labor and Pensions, and Special Committee on Aging, and the House Energy and Commerce Subcommittee on Health. Amicus Hyde has served as Chair of the House Judiciary Committee. Amici Brownback and Hyde have conducted and participated in hearings on the subject of assisted suicide in the United States. Finally, amicus Coburn is a practicing family physician.

In these various capacities, amici are directly concerned with the interpretation and enforcement of the CSA, as well as the relationship between the state and federal governments. Because of the unique perspective they offer in discerning Congress' intent, this brief focuses on the erroneous conclusion of the United States Court of Appeals for the Ninth Circuit that the CSA's legislative history supported its decision.

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[1] Pursuant to Supreme Court Rule 37.6, no person other than counsel identified on the cover participated in authoring this brief. No entities other than amici and counsel provided financial support for this brief. Further, the consent of the parties to the filing of this *amicus curiae* brief has been obtained and filed with the Clerk of the Court.

SUMMARY OF ARGUMENT

The legislative history to the CSA makes clear that in enacting and later amending the CSA, Congress was concerned with, *inter alia*, the diversion by physicians of federally-controlled substances to illegitimate uses outside the usual course of conduct of medical professionals, and that Congress saw ineffective state regulation as a significant factor in that illegitimate activity. The interpretive rule issued by the Attorney General pursuant to the CSA on November 9, 2001 (the "Interpretive Rule") states that prescribing controlled substances to assist a patient's suicide is not a "legitimate medical purpose." The Rule is entirely consistent with the statute's legislative history.

The Interpretive Rule was issued largely in response to the 1994 Oregon Death with Dignity Act (the "DWDA"), Or. Rev. Stat. § 127.800, *et seq.*, which permits physicians in that state to prescribe and dispense medications, including federally-controlled substances, to assist certain patients in committing suicide. Under the Interpretive Rule, physicians who prescribed, dispensed or administered federally-controlled substances to facilitate a patient's suicide would be subject to denial, suspension or revocation of their registrations with the Drug Enforcement Administration ("DEA") because such conduct "render[ed] [the physician's] registration . . . inconsistent with the public interest." 66 Fed. Reg. 56,607, 56,608 (Nov. 9, 2001).

As seen from the CSA's legislative history, the Interpretive Rule addresses concerns and advances goals that were considered and discussed by Congress in enacting and amending the statute. Further, by issuing the Interpretive Rule, the Attorney General acted in the role that

Congress had envisioned for the federal government. Although the legislative history does not show that Congress contemplated physician-assisted suicide specifically, this does not detract from the Attorney General's authority under the CSA to issue the Interpretive Rule.

The CSA would not apply (and actions taken pursuant to it by the Attorney General would not be authorized) if a state decided to permit assisted suicide but ensured that it would somehow occur without the involvement of DEA-registered physicians prescribing controlled substances. However, that is not the case here. Where a state seeks to permit DEA-registered physicians to assist their patients in committing suicide by prescribing controlled substances, the CSA authorizes the Attorney General to speak to whether this is a legitimate medical purpose. The Interpretive Rule is consistent with the CSA's legislative intent and a reasonable response to the DWDA.

ARGUMENT

Upholding an injunction against enforcement of the Interpretive Rule, the Ninth Circuit mistakenly concluded that the Interpretive Rule conflicted with the CSA's legislative history and that the Attorney General had exceeded his authority by issuing the Rule. *Oregon v. Ashcroft*, 368 F.3d 1118, 1127 (9th Cir. 2004) ("The CSA's legislative record confirms that the Attorney General has exceeded the scope of his authority" under the statute), *cert. granted*, 125 S. Ct. 1299 (2005). To reach this conclusion, the Ninth Circuit ignored the importance of amendments made to the CSA in 1984 and focused primarily on legislative history predating those amendments. *Id.* at

1128. The Ninth Circuit sought to characterize the 1984 amendments as little more than an effort to tidy up "loopholes" in the CSA, but acknowledged that the amendments "authorize[ed] the Attorney General to revoke physician registrations without depending on state licensing boards." *Id.* at 1129 (citing S. Rep. No. 98-225, at 260-62 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3442-44). What the Ninth Circuit failed to acknowledge was that the Attorney General issued the Interpretive Rule pursuant to this independent authority.

The Ninth Circuit tried to buttress its flawed conclusion by exaggerating the significance of legislative history from 1974 that discussed the role of the Secretary of Health and Human Services ("HHS") in registering practitioners who conduct treatment programs for narcotic addicts, which was entirely unrelated to the issue before the Court. Completing its erroneous analysis, the Ninth Circuit asserted that the legislative record supported its belief that the Attorney General was required not only to review and consider relevant Oregon law (which he did do), but also to solicit and obtain specific input from the state before he could issue the Interpretive Rule; however, this assertion makes little sense in light of the 1984 amendments, which, as the Ninth Circuit recognized, were expressly intended to permit the Attorney General to take action *independent of state authorities.*

The Ninth Circuit's reading of the CSA and its relevant legislative history was overly narrow and ultimately, mistaken. A review of the full legislative history establishes that it squarely supports the Attorney General's interpretation of the CSA and the Interpretive Rule was fully consistent with congressional intent.

I. A REVIEW OF THE LEGISLATIVE HISTORY IS INSTRUCTIVE FOR DISCERNING CONGRESSIONAL INTENT BEHIND THE CSA.

Among the interpretive tools available for determining the Congressional intent underlying a statute is the statute's legislative history. *See, e.g., Barnhart v. Walton*, 535 U.S. 212, 220 (2002); *Dep't of Commerce v. United States House of Representatives*, 525 U.S. 316, 342-43 (1999); *Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon*, 515 U.S. 687, 704-07 (1995); *Negonsott v. Samuels*, 507 U.S. 99, 104-05 (1993). A review of legislative history may be especially appropriate where, as here, the relevant statutory language is broad and susceptible to more than one meaning. *See, e.g., West v. Gibson*, 527 U.S. 212, 219-20 (1999); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432-35 (1987). Further, this Court has looked to legislative history in determining whether Congress intended for the meaning of terms in a federal statute to depend upon state law, which is also at issue in this case. *See, e.g., Lewis v. United States*, 523 U.S. 155, 170-71 (1998); *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 44-45 (1989); *Dickerson v. New Banner Institute, Inc.*, 460 U.S. 103, 119 (1983).

The Ninth Circuit, as well as the district court below, cited the CSA's legislative history to reach their decisions. However, read together and in context, statements by the sponsors and others in Congress at the time the CSA was enacted in 1970 and amended in 1984, as well as reports from the House, Senate and conference committees, provide ample support for the Interpretive Rule.

II. THE CSA'S LEGISLATIVE HISTORY CLEARLY SHOWS THAT CONGRESS INTENDED THE FEDERAL GOVERNMENT TO PLAY AN ACTIVE ROLE IN REGULATING THE PRESCRIPTION AND DISPENSING OF CONTROLLED SUBSTANCES BY PHYSICIANS.

As seen from the legislative history, Congress viewed the states as the first line of defense under the CSA against the misuse of controlled substances. The legislative history to the CSA also shows that Congress envisioned a central role for the federal government in establishing and enforcing its own standard as to what constitutes such misuse. This role necessarily required that the federal government be able to enforce its standard when a state could not or would not do so.

A. The CSA Enhanced The Federal Government's Long-Standing Role As The Regulator Of Controlled Substances.

While states have traditionally regulated the practice of medicine, the federal government has traditionally regulated the use of controlled substances. *See generally* Jonathon Erlen & Joseph F. Spillane, *Federal Drug Control: The Evolution of Policy and Practice* (2004). Since the 1914 Harrison Act, the federal government has played a significant role in controlling the prescription and dispensing by physicians of toxic, addictive narcotics. Under the Harrison Act, "every person" who imported, manufactured, dispensed or in any way distributed opium, coca leaves or their derivatives, was required to register with the Internal Revenue Service, and pay taxes on such activity. *See* Law of December 7, 1914, ch. 1 (codified as amended at 21 U.S.C. §§ 801-971). Physicians were allowed to dispense or

distribute the drugs regulated by the Harrison Act provided that they registered with the IRS, acted "in the course of [their] professional practice only," and maintained records "of all such drugs dispensed or distributed." *Id.* at ch. 1, § 2(a).

The CSA was Congress' attempt to collect and rationalize the Harrison Act and some 50 other pieces of legislation that had been enacted over the years for the purpose of regulating controlled substances. *See United States v. Rosenberg*, 515 F.2d 190, 196 (9th Cir. 1975); *United States v. Upthegrove*, 504 F.2d 682, 688 n.10 (6th Cir. 1974); *see also* H.R. Rep. No. 91-1444, at 4 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571. Further, Congress "intended the CSA to strengthen rather than to weaken the prior drug laws." *United States v. Moore*, 423 U.S. 122, 139 (1975); *see also United States v. Steinberg*, 525 F.2d 1126, 1133 (2d Cir. 1975).

Congress enacted the CSA as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Pub. L. No. 91-513, § 100, 84 Stat. 1236, 1242 (amended 1984). Congress "designed [the CSA] to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs." 1970 U.S.C.C.A.N. at 4589. The CSA created a comprehensive system for federal regulation of such substances, charging the Attorney General and the Bureau of Narcotics and Dangerous Drugs (forerunner to the DEA) with responsibility for administering the system.

Under the CSA, the differing varieties of controlled substances were separated into five categories, ranging

from Schedule I substances, which had no accepted medical use and could be used only in limited situations, to Schedule II, III, IV, and V substances, which had recognized uses and could be manufactured, distributed, and used, subject to the statute's limitations. Pub. L. No. 91-513, § 202 (Schedules I-V), 84 Stat. 1236, 1248-53. Marijuana and heroin were Schedule I substances, for example, while Schedule V included substances such as cough medicine with codeine.[2] Pub. L. No. 91-513, § 202 (Schedules I-IV), 84 Stat. 1236, 1247-1252. The CSA imposed "tighter controls" on the use of "drugs providing serious addiction or abuse problems (those listed in schedules I and II)." H.R. Rep. No. 91-1444, at 4 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4569. The CSA authorized the Attorney General to add, remove or transfer substances to or between the schedules based on procedures established by the statute. Pub. L. No. 91-518, § 201(a)(1), 84 Stat. 1236, 1245 (21 U.S.C. § 802(5)).

Discussing the criteria to be used by the Attorney General in exercising his authority under the CSA to determine the appropriate schedules for different substances, the

[2] Schedule II drugs are highly addictive, but have accepted medical uses. Pub. L. No. 91-513 § 202(b)(2), 84 Stat. 1236, 1247. The two most commonly-prescribed drugs used to assist suicide under the DWDA are pentobarbital and secobarbital, *see* Oregon Dep't of Human Servs., Off. of Disease Prevention and Epidemiology, *Seventh Annual Report on Oregon's Death With Dignity Act* 14 (2005) (*available at*: http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf); Press Release, Oregon Dep't of Human Servs., Oregon Public Health Servs., *Fewer Oregonians Used Death With Dignity Act in 2001* (Feb. 6, 2002) (*available at*: www.ohd.hr.state.or.us/news/2002/0206pas.htm), which fall into Schedule II, *see* 21 C.F.R. § 1308.12(e). Thus, the DWDA conflicts most directly with the registration requirements and other controls relating to Schedule II drugs.

House Report noted, "Misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use, are regarded as indicative of a drug's potential for abuse." 1970 U.S.C.C.A.N. at 4602. Although this reference in the legislative history was not in the context of physician-assisted suicide, it establishes that Congress intended that, in exercising regulatory authority under the CSA, the Attorney General could consider whether a controlled substance was being used to commit suicide.

Besides classifying controlled substances into different schedules, the Attorney General's duties under the CSA included monitoring the use of controlled substances through the registration of manufacturers, physicians, pharmacies, and others. The CSA required all "legitimate handlers" (*e.g.*, physicians) to register with the federal government. Pub. L. No. 91-513, § 302(a), 84 Stat. 1236, 1253. Under the CSA, registration was considered "a matter of right where the individual . . . is engaged in activities involving these drugs which are authorized or permitted under State law." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4590. The CSA authorized the Attorney General to deny, suspend or revoke a physician's registration for three reasons:

1. falsification of an application to dispense, distribute, or manufacture a controlled substance;

2. a felony conviction under state or federal law relating to a controlled substance; or

3. denial, revocation, or suspension of a state license or registration.

Pub. L. No. 91-513, §§ 303(f) & 304(a), 84 Stat. 1236, 1255. Two of these grounds depended in whole or in part on state enforcement and, in 1984, Congress acted to repair "leaks" in the closed system that resulted from this overreliance on state law.

Nonetheless, even before the 1984 amendments, the CSA (and its original implementing regulations[3]) provided clear authority for the Attorney General to regulate physician conduct in prescribing controlled substances. "[T]he scheme of the [CSA], viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice' .... [In addition,] [o]ther provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits." *Moore*, 423 U.S. at 140-42.

B. The 1974 Amendments Distinguished Between The Roles Of HHS And The Attorney General With Regard To Treatment Programs For Narcotics Addicts And Are Irrelevant To The Issue Before This Court.

In the Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124, Congress amended the CSA "to provide for the registration of practitioners conducting

[3] In 1971, the Bureau of Narcotics and Dangerous Drugs promulgated the initial regulations under the CSA. The regulations included standards for prescribing controlled substances: "A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the *usual course of his professional practice*." 21 C.F.R. § 1306.04(a) (emphasis added). The Interpretive Rule was based on the Attorney General's interpretation of this regulation. *See* 66 Fed. Reg. at 56,608.

narcotic treatment programs." H.R. Rep. No. 93-884, at 1 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3029. The Narcotic Addict Treatment Act created, *inter alia*, a registration process for the use of controlled substances in treating addicted persons through, for example, methadone maintenance and detoxification programs, that was separate and in addition to the customary registration under the CSA. 1974 U.S.C.C.A.N. at 3029-3030; *see also* 21 U.S.C. § 823(g). The Narcotic Addict Treatment Act is irrelevant to the issue currently before this Court, which concerns the customary registration process under the CSA. Thus, not surprisingly, the Ninth Circuit's conclusion from the legislative history to the 1974 amendments that the Secretary of HHS had ultimate authority to make "'[a]ll decisions of a medical nature'" under the CSA, *Oregon*, 368 F.3d at 1128 (citing 1974 U.S.C.C.A.N. at 3034), conflicts with the language of the statute, *see, e.g.*, 21 U.S.C. § 823(f) ("The *Attorney General* may deny an application for ... registration if *he determines* that the issuance ... would be inconsistent with the public interest.") (emphasis added).[4]

[4] Under the Ninth Circuit's reasoning, the 1974 legislative history would similarly cast doubt on former Attorney General Janet Reno's conclusion that dispensing drugs to assist suicides is a legitimate medical practice under the CSA. *See* Letter from Hon. Janet Reno, Attorney General of the United States, to Hon. Henry Hyde, Chairman, Committee on the Judiciary, United States House of Representatives, at 1 (June 5, 1998) ("Adverse action against a physician who has assisted in a suicide in full compliance with the [DWDA] would not be authorized by the [CSA].").

C. The 1984 Amendments Clarified The Federal Government's Authority To Act Where States Ineffectively Regulated Physician Use Of Controlled Substances.

Although the CSA has been amended many times since 1970, *e.g.*, Narcotic Addict Treatment Act; Drug-Induced Rape Prevention and Punishment Act of 1996 (Pub. L. No. 104-305, § 1, 110 Stat. 3807); Methamphetamine Anti-Proliferation Act of 2000 (Pub. L. No. 06-310, Div. B, Title XXXVI, § 3601, 114 Stat. 1227), the most significant amendments occurred in 1984. The legislative history to the 1984 amendments makes clear that at that time, Congress had become concerned that states were not effectively handling the distribution of controlled substances by physicians and that state law alone was insufficient to prevent the diversion of controlled substances from legitimate medical uses.

Thus, Congress amended the CSA to give the Attorney General additional, independent authority to deny, suspend or revoke a physician's federal registration where he determined that the registration was "inconsistent with the public interest." *See* 21 U.S.C. §§ 823(f) & 824(a)(4), Pub. L. No. 91-513, §§ 303(f) & 304(a)(4), 84 Stat. 1236, 1254. The amendments identified five specific criteria in section 823(f) (and, by reference, section 824(a)) to be used by the Attorney General in determining whether a physician's registration was consistent with the "public interest." Although state law remained an important factor, the Attorney General was also required to consider two criteria wholly independent of state law: namely, "the [physician's] experience in dispensing ... controlled substances" and "[s]uch other conduct which may threaten the public health and safety," 21 U.S.C. § 823(f)(2) & (5).

Notably, since the enactment of the CSA in 1970, the Attorney General has had discretion to determine whether the registration of a manufacturer or distributor of controlled substances was "inconsistent with the public interest." *See* 21 U.S.C. §§ 823(a), (b), (d) & (e); *see also Am. Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 829-30 (D. D.C. 1974), *aff'd*, 530 F.2d 1054 (D.C. Cir. 1976). The 1984 amendments gave the Attorney General the same authority with regard to "practitioners," and registration was no longer "a matter of right" where a physician's conduct complied with state law.

The theme of needing to better control the distribution of controlled substances through physicians by shoring up weaknesses at the state level pervades the legislative history. For example, the House Report accompanying the amendments stated,

> Unfortunately, experience under the [CSA] over the past decade has demonstrated that the same strong regulatory authority to maintain a 'closed' distribution chain does not exist at the practitioner level.... Under current law, the grounds for denial or revocation of the registration of a practitioner are very limited. Indeed, the Attorney General must presently grant a practitioner's registration application unless his State license has been revoked or he has been convicted of a felony drug offense, *even though such action may clearly be contrary to the public interest.*

H.R. Rep. No. 98-1030, at 261-62 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3443-44 (emphasis added). Similarly, Representative Hamilton Fish, a sponsor of the 1984 amendments, stated, "The most serious diversion problem today exists at the retail level. States have primary

responsibility for the licensing of physicians and pharmacists. State policing of these activities, as well as peer review within the profession, have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate." 130 Cong. Rec. H9680 (daily ed. Sept. 18, 1984).

During discussion in the House, Representative Benjamin Gilman stated that the amendments would "make it easier for the Drug Enforcement Administration to suspend or revoke the authority of physicians and pharmacists who write or dispense prescriptions in a way that is threatening to the public health or safety." *Id.* at H9681. Similarly, Representative Hughes (also a House sponsor) stated that the amended CSA "gives to DEA greater latitude to suspend or revoke the registration of a practitioner [who] dispenses drugs in a manner that threatens the public health and safety." *Id.* at H9679.

At a hearing before a House subcommittee considering the amendments, the DEA testified that the expanded federal authority to revoke a physician's registration was "one of the most important sections of the bill," not only because of inadequate state enforcement but also because "many controlled drug violations . . . are not felonies under state law and therefore cannot be used in a DEA revocation action." *Dangerous Drug Diversion Control Act of 1984*: Hearing on H.R. 5656 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 403-04 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

In the Senate, sponsor Strom Thurmond noted that, as originally enacted, the CSA

> provides necessary regulation of manufacturers and distributions, but it does not adequately cover the practitioner level of the distribution chain, the level at which 80 to 90 percent of current diversion of drugs into illicit markets takes place. . . . [The 1984 amendments] *expand[] the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner's own jurisdiction.*

130 Cong. Rec. S758 (daily ed. Feb. 2, 1984) (emphasis added).

These amendments expanding federal authority received bipartisan support in Congress. *See, e.g.*, 130 Cong. Rec. H9680-81 (daily ed. Sept. 18, 1984) (statements of Reps. Hughes and Sawyer). The amendments were approved by wide margins, passing in the Senate on February 2, 1984 on a vote of 91 to 1, *see* 130 Cong. Rec. S733, 741, and in the House on September 18, 1984 on a vote of 392 to 1, *see* 130 Cong. Rec. H9742-9743 (daily ed. Sept. 18, 1984). The President signed the legislation, and it became law on October 12, 1984. *See* Pub. L. 98-473, Title II § 501 (1984), 98 Stat. 2068.

The legislative history to the 1984 amendments, along with the amendments themselves, make clear that the "public interest" standard was intended as a requirement independent of and in addition to state felony law and state medical licensing regulations, and that the Attorney General was to determine whether it was in the public interest for a physician to be registered to prescribe controlled substances. The "public interest" provision clarified, if not increased greatly, the Attorney General's existing authority to take action even where a practitioner was in compliance with state law. As the Ninth Circuit was forced to acknowledge, "the 1984 amendments to the CSA . . . extend the Attorney General's authority over

federal registration of practicing physicians . . . " *Oregon*, 368 F.3d at 1129. In issuing the Interpretive Rule, the Attorney General properly exercised this extended authority.

D. The Interpretive Rule Is Based Upon A Reasonable Interpretation Of The CSA's Legislative History.

In light of the legislative intent behind the CSA shown by these congressional reports and comments, it seems difficult to conclude that the Attorney General lacked authority to issue the Interpretive Rule, or that the Rule is somehow contrary to the statute's purpose. In fact, both the 1984 amendments and the Interpretive Rule were federal responses to leaks in the closed system at the state level that allowed physicians to divert controlled substances to improper ends: the 1984 amendments responded to the problem in the states generally, while the Interpretive Rule responded to the problem in a specific state.

Since the 1984 amendments, the following standards have been among those with which a physician must comply to prescribe federally-controlled substances:

1. Any prescription must be issued for a "legitimate medical purpose" and while the physician is acting within the "usual course of his [or her] professional practice," 21 C.F.R. § 1306.04(a); and

2. The physician must not commit acts that cause his or her registration to be inconsistent with the "public interest," 21 U.S.C. §§ 823(f) & 824(a)(4).

With the broad phrases "legitimate medical purpose," "usual course of professional practice," and "public health and safety," the CSA and its implementing regulations leave room for further definition before these provisions can be enforced as a practical matter.

Gaps and ambiguities created by such broad terms can be filled in by the Attorney General based on a reasonable interpretation of their meaning. *See Nationsbank of North Carolina, N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995) (*citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.* 467 U.S. 837, 843-44 (1984)). To fill in gaps in the CSA and its regulations, the Attorney General can look to the statute's legislative history as one tool for discerning Congress' intent. *See Chevron*, 467 U.S. at 851-53.

Here, in concluding that physicians who prescribe controlled substances to terminate a person's life are not acting for a legitimate medical purpose or in the usual course of their professional practice, and that it is not in the public interest for such physicians to be able to continue to issue prescriptions, the Interpretive Rule fits comfortably within the congressional intent reflected by the relevant legislative history. Besides the statements described in Sections II(A) and (C) above, the legislative history also contains numerous references to the diversion of narcotic and depressant substances out of the legitimate system, the public danger caused by drugs prescribed by physicians for improper reasons, and the large numbers of deaths annually due to overdoses of prescription drugs. *See, e.g.*, 130 Cong. Rec. S9681-82 (daily ed. Feb. 2, 1984).

Notwithstanding the broader public debate regarding the practice of physician-assisted suicide generally, the

dispositive legal question before the Ninth Court was a fairly pedestrian issue of administrative law: "is the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) entitled to deference?" *Oregon*, 368 F.3d at 1131 (Wallace, *J.*, dissenting). Based on legislative history (as well as the statutory language and other sources, *see generally* Memorandum from Deputy Assistant Attorney General Sheldon Bradshaw to Hon. John Ashcroft, "Whether Physician-Assisted Suicide Serves a 'Legitimate Medical Purpose' Under the Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act" (June 27, 2001) ("DAAG Memorandum")[5]), the Attorney General's issuance of the Interpretive Rule was fully within his authority under the CSA and it was entirely reasonable for him to exclude physician-assisted suicide from permissible practices under the CSA and section 1306.04(a). Thus, the Ninth Circuit should have deferred to the Attorney General's interpretation.

E. The Federal Government's Role As Regulator Of Controlled Substances Does Not Displace The States' Role As Primary Regulators Of The Practice Of Medicine.

Congress knew when it enacted the CSA that enforcement of the statute would result in federal regulation of certain aspects of the practice of medicine, which as a general matter had always been considered primarily a state responsibility. Discussing the CSA in 1970, a House Report acknowledged the problem, but concluded that it

[5] The Attorney General relied on the DAAG Memorandum in issuing the Interpretive Rule, and the Rule incorporates it by reference. *See* 66 Fed. Reg. at 56,608.

could not be avoided: "Although the Committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last fifty years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinion of federal prosecutors of what constitutes appropriate methods of professional practice." H.R. Rep. No. 91-1444, Part 1, at 51 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4581.

However, Congress never intended to displace the states as primary regulators of physicians, and the CSA was never intended to result in a wholesale nationalizing of the practice of medicine. For example, since its enactment in 1970, the CSA has provided that it does not "occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision [of the CSA] and that State law so that the two cannot consistently stand together." 21 U.S.C. § 903. Even after the 1984 amendments, Congress intended that the DEA "would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applications." H.R. Rep. No. 98-1030 pt. B, at 267 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449; *see also* 21 U.S.C. § 823(f)(1). Further, "[r]egistration of a physician under the [CSA] is a matter entirely separate from a physician's State license to practice medicine. Therefore, revocation [of] registration only precludes a physician from dispensing substances controlled under the [CSA] and does not preclude his dispensing other prescription drugs or his continued

practice of medicine." H.R. Rep. No. 98-1030, at 267 n.40 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449 n.40.

Thus, for purposes other than the CSA (and leaving aside the issue of whether other federal laws would be implicated), states may have a right to decide whether physician-assisted suicide is a legitimate medical practice. Nonetheless, with regard to prescribing and dispensing federally-regulated substances, the CSA leaves final determination of what constitutes a "legitimate medical purpose" to the Attorney General. Congress realized that not only would federal regulation be concurrent with state regulation but that, in some situations, it would necessarily supersede state law. The result here is that the DWDA must yield to the Interpretive Rule and, like all other DEA-registered physicians in the United States, DEA-registered physicians in Oregon cannot requisition federally-controlled substances to facilitate their patients' deaths.

In determining whether physician-assisted suicide is "inconsistent with the public interest," the Attorney General satisfied the requirement of section 823(f) that he review and consider, *inter alia*, Oregon law. *See* DAAG Memorandum, at 1-2, 6, 14, 20 (reviewing DWDA and its history, legal opinion of Oregon Deputy Attorney General, and effect of proposed interpretation on Oregon physicians). Contrary to the Ninth Circuit's conclusion, the CSA does not require that he "solicit input" from Oregon before issuing the Interpretive Rule, *Oregon*, 368 F.3d at 1129, and, at bottom, the Ninth Circuit merely complains that

the manner in which the Rule was issued was impolitic.[6] Whether this complaint is accurate or not is irrelevant as a legal matter.

Finally, a decision by this Court to affirm the Ninth Circuit's decision will not result in a clean demarcation between the authority of Oregon and the federal government, respectively, to define what constitutes a legitimate medical practice. Instead, Oregon will merely have carved out of the CSA a specific purpose for controlled substances (*i.e.*, assisting suicides) that is governed solely by state law. In enforcing the CSA in Oregon, the federal government will be placed in the position of having to differentiate between "legitimate" and "illegitimate" deaths caused by physicians prescribing controlled substances in the state. Moreover, effective regulation of controlled substances on a national basis will become more difficult if individual states can opt out of the CSA where they disagree with the federal government about proper uses for the substances.

III. THE ATTORNEY GENERAL HAS THE AUTHORITY TO DETERMINE WHETHER PHYSICIAN-ASSISTED SUICIDE VIOLATES THE CSA, NOTWITHSTANDING THE ABSENCE OF SPECIFIC REFERENCES TO THE PRACTICE IN THE LEGISLATIVE HISTORY.

As noted by the Ninth Circuit, much of the legislative history from the CSA's initial enactment reflects a specific

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[6] As noted by the dissent, specific input would be appropriate if and when a particular physician's registration was being reviewed in light of the Interpretive Rule, which is not the situation here. *See Oregon*, 368 F.3d at 1139-40 (Wallace, *J.*, dissenting).

concern with "crack[ing] down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls." *Oregon*, 368 F.3d at 1128 (quoting 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970)). Further, although Congress identified "suicides and attempted suicides" as improper uses of controlled substances, *see* 1970 U.S.C.C.A.N. at 4602, nothing in the history to the 1970 enactment or the 1984 amendments establishes that Congress ever had in mind the specific "practice" of physician-assisted suicide. Nonetheless, these aspects of the legislative history do not support the Ninth Circuit's conclusion that the Interpretive Rule is contrary to the CSA and outside the Attorney General's authority under the CSA.

The application of a statute to circumstances beyond those specifically contemplated by Congress at the time of enactment is not unusual or improper. For example, in *H.J. Inc. v. Northwestern Bell Telephone Co.*, 492 U.S. 229, 245-8 (1989), the Supreme Court acknowledged that Congress' target in enacting the RICO statute "was the perceived need to combat organized crime. But Congress for cogent reasons chose to enact a more general statute, one which, although it had organized crime as its focus, was not limited in application to organized crime." *Id.* at 248. As one congressman noted during debate on the statute, "'Whatever the limited occasion for the identification of a problem, the Congress has the duty of enacting a principled solution to the entire problem. Comprehensive solutions to identified problems must be translated into well integrated legislative programs.'" *Id.* at 246-47 (quoting 116 Cong. Rec. 18913-18914 (1970) (Sen. McClellan)).

Similarly, in *Browder v. United States*, 312 U.S. 335, 339-40 (1941), the Supreme Court upheld a criminal conviction where the defendant used a fraudulently-obtained passport to re-enter the United States. The defendant argued that at the time the statute was enacted, passports were not customarily used by citizens to assure easy re-entry and thus, Congress did not intend to punish the conduct for which he was convicted. The Court stated,

> There is nothing in the legislative history to indicate that Congress considered the question of use [of passports] by returning citizens. Old crimes, however, may be committed under new conditions. Old laws apply to changed situations. The reach of the act is not sustained or opposed by the fact that it is sought to bring new situations under its terms. While a statute speaks from its enactment, even a criminal statute embraces everything which subsequently falls within its scope.

312 U.S. at 339-40 (footnote omitted); *see also Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) ("male-on-male sexual harassment in the workplace was assuredly not the principal evil Congress was concerned with when it enacted Title VII [of the Civil Rights Act of 1964] but statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils"); *United States v. Southwestern Cable Co.*, 392 U.S. 157, 172-73 (1968) (FCC has jurisdiction to regulate community antenna television systems even though when statute creating FCC was enacted in 1934, Congress could not envision development of such systems).

Like the federal statutes in *H.J. Inc.*, *Browder*, *Oncale* and *Southwestern Cables*, Congress drafted the CSA with sufficient breadth such that its language permits reasonable applications not specifically contemplated by Congress. The mere absence of a specific reference to physician-assisted suicide in the legislative history cannot preclude the Attorney General from determining whether it is a legitimate medical practice under the CSA. Demanding proof from the legislative history that Congress envisioned the precise conduct permitted by the DWDA is unreasonable and the purported lack of such "proof" is not a proper ground for enjoining the Interpretive Rule. *See Rust v. Sullivan*, 500 U.S. 173, 189-90 (1991).

If anything, the absence of specific discussions of physician-assisted suicide likely reflects the simple fact that both when the CSA was passed and later amended, such a practice was beyond what Congress contemplated as a reasonable possibility. The 1970 House Report's reference to "misuse of a drug in suicides and attempted suicides" presumes that such use would be a "misuse." In fact, it seems that until former Attorney General Janet Reno issued her written opinion on June 5, 1998 creating an exception from the CSA for Oregon, the general understanding in Congress was that assisted suicide could not be considered a legitimate medical practice.[7]

[7] Certainly the DEA thought so. *See* Letter from Hon. Thomas A. Constantine, Administrator of the Drug Enforcement Administration of the United States To Hon. Henry J. Hyde, Committee on the Judiciary, United States House of Representatives (Nov. 5, 1997) (concluding that prescribing a controlled substance with the intent to assist suicide was not a legitimate medical purpose and would violate the CSA); *see also Hugh I. Schade, M.D., Denial of Application*, 60 Fed. Reg. 56,354 (Nov. 8, 1995) (denying registration on ground of "public health and safety"

(Continued on following page)

For example, in 1997 Congress passed the Assisted Suicide Funding Restriction Act, which President Clinton signed into law on April 30 of that year. Pub. L. 105-12, 111 Stat. 23. The Assisted Suicide Funding Restriction Act directly prohibits the use of federal funds for the purpose of causing or assisting in causing the death of any individual. *Id.* § 3(a)(1). In passing the Act, Congress stated that its purpose was "*to continue current federal policy* by providing explicitly that federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual." Pub. L. No. 105-12, § 2(b), 111 Stat. 23 (emphasis added). And this remains federal policy today. *See* Health & Human Servs., *Medicare Benefit Policy Manual*, ch. 16, § 20 ("A health care item or service for the purpose of causing, or assisting to cause, the death of any individual (assisted suicide) is not covered" by the Medicare program.) (*available at*: http://www.cms.hhs.gov/manuals/102_policy/bp102c16.pdf). Thus, it seems clear that, apart from the June 5, 1998 opinion, the position of the federal government has consistently been that it will not facilitate suicide.

This reasonable federal policy is consistent with the clear ethical consensus of the medical profession from enactment of the CSA through today. The positions of the American Medical Association and other medical organizations have reflected nearly uniformly the view that physician-assisted suicide is not an acceptable or legitimate medical practice. *See, e.g.*, Am. Med. Ass'n, *Code of Medical*

where physician had prescribed lethal amounts of Darvocet to depressed patient who used them to commit suicide).

Ethics § 2.211 (2005) ("[p]hysician-assisted suicide is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks" and "[i]nstead of participating in assisted suicide, physicians must aggressively respond to the needs of patients at the end of life"); Editorial, *Deadly milestone: 5 years of assisted suicide*, amednews.com, Apr. 21, 2003 (*available at*: http://www.ama-assn.org/amednews/2003/04/21/edsb0421.htm); Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992) ("Physicians must not . . . participate in assisted suicide[ ]" and "[p]hysician assisted suicide . . . is contrary to the traditional prohibition against using the tools of medicine to cause a patient's death" and includes the "potential for coercive financial and societal pressures on patients to choose suicide."); ANA Position Statement (available at: nursingworld.org/readroom/position/ethics/etsuic.htm); Task Force on the Nurse's Role in End-of-Life Decisions, Center for Ethics and Human Rights (1994) ("[s]uch an act is in violation of the Code for nurses . . . and the ethical traditions of the profession"). Notably, when the CSA was enacted, it was recommended to Congress by a Presidential Commission that under the CSA's regulations, "the definition of legitimate medical use of narcotic drugs [be] primarily . . . determined by the medical profession." H.R. Rep. No. 91-1444, at 21, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4586. In the Interpretive Rule, the Attorney General properly exercised his authority under the CSA by reasonably concurring with the medical profession that physician-assisted suicide is not a legitimate medical practice.

CONCLUSION

For the foregoing reasons, Amici Curiae respectfully request that the judgment of the Ninth Circuit be reversed.

Respectfully submitted,

DONALD A. DAUGHERTY, JR.
Counsel of Record
JOHN B. TUFFNELL
WHYTE HIRSCHBOECK DUDEK S.C.
555 E. Wells Street, Suite 1900
Milwaukee, WI 53202
(414) 273-2100

Counsel for Congressional Amici

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ALBERTO GONZALES, ATTORNEY GENERAL, IN HIS OFFICIAL CAPACITY, ET AL.,

Petitioners,

v.

STATE OF OREGON, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF AMICUS CURIAE OF THE CATHOLIC MEDICAL ASSOCIATION IN SUPPORT OF PETITIONERS AND IN SUPPORT OF REVERSAL

TERESA STANTON COLLETT
Professor of Law
University of St. Thomas
School of Law
MSL 400
1000 LaSalle Avenue
Minneapolis, MN 55403-2015
(651) 962-4973
Fax (651) 962-4996
tscollett@stthomas.edu

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
TABLE OF CONTENTS	i
TABLE OF AUTHORITIES	ii
INTEREST OF AMICUS	1
SUMMARY OF ARGUMENT	1
ARGUMENT	2
I. Defining "legitimate medical practice" in terms of national practice is consistent with the norms of the medical profession as evidenced by professional standards regarding medical education, licensure, and the liability of physicians	4
II. Abuse of prescription drugs and the need for a uniform definition of "legitimate medical purpose" for enforcement purposes supports the interpretation contained in the Ashcroft Directive	6
III. The statutory definition of drugs subject to prescription would be rendered nonsensical by including assisting with suicide as a "legitimate medical purpose."	7
CONCLUSION	10

TABLE OF AUTHORITIES

Page

CASES

Barsky v. Board of Regents, 347 U.S. 442 (1954) 7

Minnesota ex rel. Whipple v. Martinson, 256 U.S. 41 (1921) 7

Nadler v. West Park Hosp., 254 F.3d 1168 (10th Cir. 2001) 5

O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 389 F.3d 973 (10th Cir. 2004) 7

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) 4

People ex rel. Oakland County Prosecuting Atty. v. Kevorkian, 534 N.W.2d 172 (Mich. App., 1995) 10

Robinson v. California, 370 U.S. 660 (1962) 7

Shilkret v. Annapolis Emergency Hosp. Assn., 349 A.2d 245 (Md. 1975) 5

Swan v. Lamb, 584 P.2d 814 (Utah 1978) 5

United States v. Moore, 423 U.S. 122 (1975) 2

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001) 3

United States v. Rutherford, 442 U.S. 544 (1979) 3, 8, 9

Whalen v. Roe, 429 U.S. 589 (1977) 7

STATUTES

21 U.S.C. § 321(g) 3

21 U.S.C. §§ 801-904 2

TABLE OF AUTHORITIES – Continued

Page

21 U.S.C. § 812 2

21 C.F.R. § 1306.4(a) 3, 4

OTHER

David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 Drake L. Rev. 439 (1996) 2, 9

Federation of State Medical Boards, *Examinations* at http://www.fsmb.org (visited May 5, 2005) 4

National Drug Intelligence Center, *Pharmaceuticals Drug Threat Assessment* (Nov. 2004) 6

National Drug Intelligence Center, *Reducing Prescription Drug Abuse* (2004) 6

OXFORD ENGLISH DICTIONARY (2d ed. 1989) 9

Pope John Paul II, *On Faith and Reason* (1998) 1

Steven A. Wartman & John H. Littlefield, *Changes in the US Medical Licensure Examination and Impact on US Medical Schools*, 293 JAMA 424 (2005) 4

S. 5, 74th Cong., 1st Sess. § 201(b), 79 Cong. Rec. 8351 (1935) 3

INTEREST OF AMICUS[1]

The Catholic Medical Association is a professional association of American and Canadian physicians, who seek to respond to the unique responsibility belonging to all health-care personnel as guardians and servants of human life and human dignity. Its members are conscious of the fact that their patients entrust themselves to the knowledge acquired by physicians. This suggests an important tension. As Pope John Paul, II noted in *On Faith and Reason* (1998), "On the one hand, the knowledge acquired through belief can seem an imperfect form of knowledge, to be perfected gradually through personal accumulation of evidence; on the other hand, belief is often humanly richer than mere evidence, because it involves an interpersonal relationship and brings into play not only a person's capacity to know but also the deeper capacity to entrust oneself to others. . . . " *Id.* at ¶ 32. This capacity to entrust oneself to others lies at the heart of the patient-physician relationship, and at the heart of the patient-physician relationship. The Catholic Medical Association hopes to assist the Court in properly understanding the impact of this case upon that relationship.

SUMMARY OF ARGUMENT

The motivating force behind the Controlled Substances Act was to centralize the enforcement of drug laws to address the national problem of drug abuse. Congress rightly understood that an effective response would require

[1] No counsel for any party authored any portion of this brief. No persons other than amicus curiae, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consents of the parties will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

sensitivity to the legitimate role of the medical profession in fighting disease, restoring health and alleviating human suffering. It would also require uniform characterization, utilization and availability of drugs to be determined at the national level. The Attorney General's construction of the Act and the implementing regulations reflect these Congressional concerns and the reality of contemporary medical practice. In contrast, the position of the Respondents renders the national design of drug approval incoherent and federal enforcement subject to the dictates of state authorities. For these reasons the rulings of the lower courts must be reversed.

ARGUMENT

Federal regulation of drugs is based in part on the reasonable belief that "sick people must be protected from quacks, charlatans, and those who raise false hopes and take advantage of human suffering."[2] The Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-904, furthers society's goal of protecting citizens from both contemporary snake-oil salesmen and drug pushers[3] by directing the Attorney General of the United States to place prescription drugs on a statutory schedule after assessing the drugs for three factors: the drug's potential for abuse, its current accepted medical uses, and the possibility that abuse of the drug will lead to physical or psychological dependency. 21 U.S.C. § 812.

[2] David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 Drake L. Rev. 439, 450 (1996).

[3] *United States v. Moore*, 423 U.S. 122, 143 (1975) (defendant "acted as a large-scale 'pusher' not as a physician."

By including "current accepted medical uses" Congress protected the authentic autonomy of the medical profession. The history of the Federal Food, Drug, and Cosmetic Act reveals that the first bill to pass either house of Congress that was substantially similar to the present Act included within its definition of "drug" the qualification that it did not apply to "the regulation of the legalized practice of the healing art." S. 5, 74th Cong., 1st Sess. § 201(b), 79 Cong. Rec. 8351 (1935). While the definition of "drug" as ultimately enacted did not include this proviso, *see* 21 U.S.C. § 321(g) (1976), the legislative history makes clear that Congress has always sought to protect physicians' ability to treat their patients, while simultaneously insuring the efficacy and safety of drugs. In promulgating 21 C.F.R. § 1306.4(a) the Attorney General also recognized the necessary professional discretion of doctors. "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.*

The present case requires this Court to determine once again whether national or state standards determine legitimate medical practices for purposes of drug regulations. *Cf. United States v. Rutherford*, 442 U.S. 544 (1979) (no exception to FDA approval requirements for Laetrile administered only to terminally ill patients notwithstanding approval by seventeen states) and *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (federal law controls over state law regarding the distribution of marijuana).

I. DEFINING "LEGITIMATE MEDICAL PRACTICE" IN TERMS OF NATIONAL PRACTICE IS CONSISTENT WITH THE NORMS OF THE MEDICAL PROFESSION AS EVIDENCED BY PROFESSIONAL STANDARDS REGARDING MEDICAL EDUCATION, LICENSURE, AND THE LIABILITY OF PHYSICIANS.

Defining "legitimate medical practice" by national norms, rather than the isolated practice of a single state is a permissible construction of 21 C.F.R. § 1306.4(a), whether this Court examines the Ashcroft Directive with substantial deference to the judgment of the Attorney General, or under a less deferential standard. *See Oregon v. Ashcroft*, 368 F.3d 1118, 1144 (9th Cir. 2004) (Wallace, J. dissenting). The medical profession, itself, is increasingly adopting national standards for self regulation as evidenced by the pervasive use of a national admissions test for medical school, the Medical College Admission Test, and the universal requirement that students pass the United States Medical Licensing Exam in order to obtain a medical license. *See* Federation of State Medical Boards, *Examinations* at http://www.fsmb. org (visited May 5, 2005). These two tests alone tend to standardize medical school curriculum, since medical students who have successfully competed for their spots in medical school on the basis of a particular test are more likely to bring similar abilities to their medical education. Likewise medical schools insure that their faculty transmits the knowledge and skills that are necessary for students to succeed in passing the United States Medical Licensing Exam since that is the gateway to professional licensure. *See* Steven A. Wartman & John H. Littlefield, *Changes in the US Medical Licensure Examination and Impact on US Medical Schools*, 293 JAMA 424 (2005) (documenting changes in curriculum due to changes in Medical Licensure Exam).

This trend toward national standards is also evident in courts' adoption of a national standard of care for assessing attorney conduct in medical malpractice cases.

> The modern physician bears little resemblance to his predecessors. As we have indicated at length, the medical schools of yesterday could not possibly compare with the accredited institutions of today, many of which are associated with teaching hospitals. But the contrast merely begins at that point in the medical career: vastly superior postgraduate training, the dynamic impact of modern communications and transportation, the proliferation of medical literature, frequent seminars and conferences on a variety of professional subjects, and the growing availability of modern clinical facilities are but some of the developments in the medical profession which combine to produce contemporary standards that are not only much higher than they were just a few short years ago, but also are national in scope.

Shilkret v. Annapolis Emergency Hosp. Assn., 349 A.2d 245, 252 (Md. 1975). *See also Swan v. Lamb*, 584 P.2d 814, 817 (Utah 1978).

As the Tenth Circuit has noted, "The growing majority of jurisdictions employ some variation of the national standard of care: a physician has a duty to employ the same reasonable diligence, skill, competence, and prudence as a minimally competent practitioner in the same general specialty, without regard to whether the care is delivered in an urban or rural setting." *Nadler v. West Park Hosp.*, 254 F.3d 1168, 1176 (10th Cir. 2001).

With the medical profession increasingly relying upon national assessments for those who are entering the profession, and with doctors being held accountable under national standards of care, the Attorney General's use of

national norms to define "legitimate medical practice" is clearly a permissible construction of the regulations regarding the prescribing privileges of physicians.

II. ABUSE OF PRESCRIPTION DRUGS AND THE NEED FOR A UNIFORM DEFINITION OF "LEGITIMATE MEDICAL PURPOSE" FOR ENFORCEMENT PURPOSES SUPPORTS THE INTERPRETATION CONTAINED IN THE ASHCROFT DIRECTIVE.

> Nationwide, the rate of abuse for pharmaceuticals [prescription drugs] is relatively high compared with rates of abuse for other drug types. National Survey on Drug Use and Health (NSDUH) data indicate that 6.3 percent of persons aged 12 or older reported nonmedical use of any prescription-type pain reliever, tranquilizer, stimulant (including both illicit and prescription methamphetamine), or sedative (not including over-the-counter drugs) in 2003, second only to marijuana (10.6%) and much higher than cocaine (2.5%) and heroin (0.1%).

National Drug Intelligence Center, *Pharmaceuticals Drug Threat Assessment* 2 (Nov. 2004). Nearly fourteen percent of young people between the ages of 12 and 17 report having used prescription drugs for non-medical purposes at some point in their lives. National Drug Intelligence Center, *Reducing Prescription Drug Abuse* 1 (2004) at http://www.whitehousedrugpolicy.gov/news/press04/prescrip_fs.pdf (last visited at May 5, 2005). In the past ten years emergency room visits associated with narcotic pain relievers have increased 163%. *Id.* Illegal prescribing by physicians is a significant source of this problem. *Pharmaceuticals Drug Threat Assessment* at 6.

To require the Attorney General to accommodate a state's deviation from common medical practices as demanded by the Respondents in this case risks compounding the existing problem of prescription drug abuse by multiplying the applicable legal standards to be applied by law enforcement in evaluating the conduct of the prescribing physician. This lack of uniformity in drug control laws is one of the very ills that the CSA was intended to eliminate. *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 389 F.3d 973, 984 (10th Cir. 2004) (Murphy J. concurring in part and dissenting in part) (congressional findings in CSA speak to a need for uniformity in administration given the serious problem of drug abuse in the United States). The Attorney General's use of a uniform standard of "legitimate medical practice" for physicians prescribing controlled substances in all states is clearly a permissible construction of the regulations under the CSA.

III. THE STATUTORY DEFINITION OF DRUGS SUBJECT TO PRESCRIPTION WOULD BE RENDERED NONSENSICAL BY INCLUDING ASSISTING WITH SUICIDE AS A "LEGITIMATE MEDICAL PURPOSE."

In *Whalen v. Roe*, the Court stated, "It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions." 429 U.S. 589, 603 n.30 (1977), citing *Robinson v. California*, 370 U.S. 660, 664-665 (1962); *Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921); and *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). "Although the State no doubt could prohibit entirely the use of particular Schedule II drugs, it has not done so." *Id.* at 603. Schedule II drugs "have accepted uses in the amelioration of pain and in the treatment of [various diseases]" (*id.* at 593 n.8); they are safe and effective, but

are also liable to abuse. If a state may prohibit entirely the use of such drugs, then surely the government may restrict the circumstances of their use.

The contours of this case are deceptively narrow. The claim urged at present is only in support of a judgment that prohibits the federal government from interfering with access by Oregon physicians assisting terminally ill patients in accordance with that state's law. But the logic of the claim goes much further. If, as the lower courts held, state law determines the right of access to any drug, then it is difficult to see how the CSA can be enforced with respect to any drug if a state chooses to legislate to the contrary.

This Court confronted a similar issue in *United States v. Rutherford*, 442 U.S. 544 (1979) when reviewing a lower court decision that exempted the drug Laetrile from FDA approval when used by terminally ill cancer patients. Seventeen states had legalized the use of Laetrile for cancer treatment, notwithstanding the fact that the drug had not been approved by the FDA. *Id.* at 554, n. 10. The lower court had ruled that the FDA requirements of safety and effectiveness had no reasonable application to terminally ill patients, and thus doctors were free to prescribe it for cancer patients who were dying. *Id.* at 551.

In reversing the court of appeals, this Court observed, "To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals." Similarly, to accept Respondents' characterization of assisting suicide as a "legitimate medical purpose" is to render virtually meaningless the safety and efficacy analysis engaged in by the FDA

when evaluating drugs.[4] The Oxford English Dictionary defines safety as "exemption from hurt or injury." OXFORD ENGLISH DICTIONARY (2d ed. 1989). If inducing death is a legitimate use of the drug under consideration, how is the safety of that drug to be assessed? Does death become merely a possible adverse side effect for some uses, or is it simply another indicated use?

As this Court so presciently noted in the *Rutherford* case:

> If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil, and suet. In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile's current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.

442 U.S. at 558.

Similarly, if Respondents prevail in this case, lethal substances suddenly become candidates for a new category

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[4] *Cf.* David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 Drake L. Rev. 439, 448-52 (1996).

of controlled substances to be marketed to physicians and patients for suicides. Just as Dr. Kevorkian found patients for his suicide machine before he was enjoined from using it, other enterprising purveyors of death will no doubt seek to capitalize on the suffering of the terminally ill. *See People ex rel. Oakland County Prosecuting Atty. v. Kevorkian*, 534 N.W.2d 172 (Mich. App., 1995).

CONCLUSION

The Attorney General's construction of the CSA and its implementing regulations is consistent with the medical profession's increasing reliance on national norms for self-regulation, is an integral part of the enforcement of the laws prohibiting abuse of prescription drugs, and is a necessary construction to retain any coherent regulatory authority over the safety of prescription drugs. For all the foregoing reasons, Amicus respectfully urges this Court to reverse the judgment of the courts below.

Respectfully submitted,

TERESA S. COLLETT
Professor of Law
University of St. Thomas School of Law*
MSL 400
1000 LaSalle Avenue
Minneapolis, MN 55403-2015
(651) 962-4973
(651) 962-4996 FAX
tscollett@stthomas.edu

Counsel for Amicus Curiae
The Catholic Medical Association

*affiliation listed for informational purposes only

No. 04-623

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONERS

PAUL D. CLEMENT
Acting Solicitor General
Counsel of Record

PETER D. KEISLER
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

GREGORY G. KATSAS
Deputy Assistant Attorney General

DOUGLAS HALLWARD-DRIEMEIER
Assistant To The Solicitor General

MARK B. STERN
JONATHAN H. LEVY
Attorneys

Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of any state law purporting to authorize such distribution.

PARTIES TO THE PROCEEDING

Petitioners are Alberto R. Gonzales, Attorney General of the United States, Karen Tandy, Administrator of the Drug Enforcement Administration, Kenneth W. McGee, Assistant Special Agent-In-Charge of the Portland Office of the Drug Enforcement Administration, the United States of America, the United States Department of Justice, and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, David Malcolm Hochhalter, John Doe #1, and Don W. James.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statutory provisions involved	1
Statement	2
Summary of argument	11
Argument:	
I. The Controlled Substances Act establishes a comprehensive and uniform national system for regulating controlled substances, and the Attorney General's interpretive ruling implementing the Act is supported by the overwhelming weight of authority	14
A. The prohibition on dispensing controlled substances for other than a "legitimate medical purpose" in the "usual course of professional treatment" is central to the regulatory scheme established by the Controlled Substances Act	14
B. The Attorney General's conclusion that facilitating an individual's suicide is not a "legitimate medical purpose" in "treatment" for purposes of the Controlled Substances Act is supported by the overwhelming weight of authority	18
1. The language of the CSA demonstrates that Congress did not authorize physicians to prescribe controlled substances for the purpose of ending their patients' lives	18

Table of Contents—Continued: Page

2. The Attorney General's interpretation of the phrases "legitimate medical purpose" and "professional treatment" to exclude physician-assisted suicide is supported by historical tradition and the near-unanimity of state and federal authority 21

C. The Controlled Substances Act has a uniform meaning, determined by federal law, throughout the United States 24

1. There is a presumption in favor of a uniform national standard 25

2. Judicial decisions interpreting the CSA confirm that it provides a uniform federal-law standard 27

3. The CSA's legislative history confirms that there is a uniform federal-law standard 33

II. The court of appeals' rejection of the Attorney General's interpretive ruling was based on a fundamental misunderstanding of the applicable principles of statutory construction 37

A. The Controlled Substances Act does not intrude upon the core sovereignty of the States in a way that implicates the clear statement rule of *Gregory* v. *Ashcroft* 37

B. The presumption against preemption of state law furnishes no basis for refusing to give uniform effect to a provision of federal law 43

Table of Contents—Continued: Page

C. The additional reasons given by the court of appeals for invalidating the Attorney General's interpretive ruling are also flawed 45

Conclusion 50

TABLE OF AUTHORITIES

Cases:

Alliance for Cannabis Therapeutics v. *DEA*, 15 F.3d 1131 (D.C. Cir. 1994) 21, 29

Asgrow Seed Co. v. *Winterboer*, 513 U.S. 179 (1995) 18

Auer v. *Robbins*, 519 U.S. 452 (1997) 21

California Div. of Labor Standards Enforcement v. *Dillingham Contrs. N.A., Inc.*, 519 U.S. 316 (1997) 43

California Fed. Sav. & Loan Ass'n v. *Guerra*, 479 U.S. 272 (1987) 43

Caron v. *United States*, 524 U.S. 308 (1998) .....

Chevron U.S.A. Inc. v. *NRDC, Inc.*, 467 U.S. 837 (1984) 21

City of Edmonds v. *Oxford House, Inc.*, 514 U.S. 725 (1995) 39

Dickerson v. *New Banner Inst., Inc.*, 460 U.S. 103 (1983) 27

FDIC v. *Meyer*, 510 U.S. 471 (1994) 18

Gately v. *Massachusetts* 2 F.3d 1221 (1st Cir. 1993) 39

Gettman v. *DEA*, 290 F.3d 430 (D.C. Cir. 2002) 29

Gooding v. *United States*, 416 U.S. 430 (1974) 26

Gregory v. *Ashcroft*, 501 U.S. 452 (1991) 9, 13, 37, 38, 39

Hammer v. *Dagenhart*, 247 U.S. 251 (1918) 40

Hodel v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264 (1981) 39

Jerome v. *United States*, 318 U.S. 101 (1943) 25

Cases—Continued: Page

Kane v. *Kulongoski*, 871 P.2d 993 (Or. 1994) 6, 22, 44
Lambert v. *Yellowley*, 272 U.S. 581 (1926) 40
Linder v. *United States*, 268 U.S. 5 (1925) 37, 40
Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1976) 42, 43
Minor v. *United States*, 396 U.S. 87 (1969) 40
Mississippi Band of Choctaw Indians v. *Holyfield*, 490 U.S. 30 (1989) 10, 11, 25
Reina v. *United States*, 364 U.S. 507 (1960) 41
Reves v. *Ernst & Young*, 494 U.S. 56 (1990) 25
Robbins v. *Footer*, 553 F.2d 123 (D.C. Cir. 1977) 36
Salt Lake Tribune Publ'g Co. v. *Management Planning, Inc.*, 390 F.3d 684 (10th Cir. 2004) 25
Solid Waste Agency v. *United States Army Corps Eng'rs*, 531 U.S. 159 (2001) 9, 41
Thomas Jefferson Univ. v. *Shalala*, 512 U.S. 504 (1994) 21
Trawick v. *DEA*, 861 F.2d 72 (4th Cir. 1988) 21
United States v. *Chin*, 795 F.2d 496 (5th Cir. 1986) 17
United States v. *Daniel*, 3 F.3d 775 (4th Cir. 1993), cert. denied, 510 U.S. 1130 (1994) 16, 17, 32
United States v. *Darby*, 312 U.S. 100 (1941) 40
United States v. *Doremus*, 249 U.S. 86 (1919) 33
United States v. *Hammond*, 781 F.2d 1536 (11th Cir. 1986) 17
United States v. *Hayes*, 794 F.2d 1348 (9th Cir. 1986), cert. denied, 479 U.S. 1086 (1987) 32
United States v. *Hughes*, 895 F.2d 1135 (6th Cir. 1990) 17
United States v. *Jamieson*, 806 F.2d 949 (10th Cir. 1986) 16
United States v. *Kaplan*, 895 F.2d 618 (9th Cir. 1990) 16
United States v. *Kennedy*, 107 Fed. Appx. 518 (6th Cir. 2004) 32

Cases—Continued: Page

United States v. *Kirk*, 584 F.2d 773 (6th Cir.), cert. denied, 439 U.S. 1048 (1978) 17
United States v. *Leal*, 75 F.3d 219 (6th Cir. 1996) 32, 33, 35, 42
United States v. *Lot 5, Fox Grove*, 23 F.3d 359 (11th Cir. 1994) 39
United States v. *Moore*, 423 U.S. 122 (1975) ..... *passim*
United States v. *Nelson*, 383 F.3d 1227 (10th Cir. 2004) 17
United States v. *Norris*, 780 F.2d 1207 (5th Cir. 1986) 32
United States v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001) 3, 12, 28, 41, 44
United States v. *Pelzer*, 312 U.S. 399 (1941) 25
United States v. *Plesons*, 560 F.2d 890 (8th Cir. 1977) 17
United States v. *Rosenberg*, 515 F.2d 190 (9th Cir.), cert. denied, 423 U.S. 1031 (1975) 17, 32, 35, 42
United States v. *Tran Trong Cuong*, 18 F.3d 1132 (4th Cir. 1994) 17
United States v. *Turley*, 352 U.S. 407 (1957) 25
United States v. *Vamos*, 797 F.2d 1146 (2d Cir. 1986), cert. denied, 479 U.S. 1036 (1987) 32
United States v. *Webb*, 249 U.S. 96 (1919) 33
Vacco v. *Quill*, 521 U.S. 793 (1997) 20, 22
Washington v. *Glucksberg*, 521 U.S. 702 (1997) 8, 21, 22, 23, 39
Webb v. *United States*, 249 U.S. 96 (1919) 19, 40

Constitution, statutes and regulations:

U.S. Const.:
Art. I, § 8, Cl. 3 (Commerce Clause) 40, 41
Art. VI, Cl. 2 (Supremacy Clause) 43, 44
Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, 111 Stat. 23 24

Statutes and regulations—Continued: Page

Children's Health Act of 2000, Pub. L. No. 106-310, Tit. XXXVI, Div. B, § 3652, 114 Stat. 1239 (21 U.S.C. 830(b)(3)) 17
Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236:
Pmbl., 84 Stat. 1236 2
§ 303(f), 84 Stat. 1253 34
Controlled Substances Act, 21 U.S.C. 801 *et seq.* 2
21 U.S.C. 801(1) 14, 15, 20, 26, 46
21 U.S.C. 801(2) 26, 45
21 U.S.C. 801(6) 26
21 U.S.C. 802(10) 2, 15
21 U.S.C. 802(12) 45
21 U.S.C. 802(21) 2, 5, 15, 17
21 U.S.C. 811 ..... 4, 46
21 U.S.C. 811(a) 15, 26, 28
21 U.S.C. 812 3
21 U.S.C. 812(b) 15, 20, 26, 27, 45
21 U.S.C. 812(b)(1) 3
21 U.S.C. 812(b)(1)(B) 7, 15
21 U.S.C. 812(b)(2)(B) 3, 5, 15, 30
21 U.S.C. 812(b)(3)(B) 3, 5, 15
21 U.S.C. 812(b)(4)(B) 3, 5, 15
21 U.S.C. 812(b)(5)(B) 3, 5, 15
21 U.S.C. 812(c) 4
21 U.S.C. 821 4
21 U.S.C. 822(a)(2) 2
21 U.S.C. 822(b) 3, 26
21 U.S.C. 823(a)(1) 16, 46
21 U.S.C. 823(f) 2, 10, 15, 34, 46, 49
21 U.S.C. 823(f)(3) 10
21 U.S.C. 823(f)(4) 10, 49
21 U.S.C. 823(f)(5) 10, 46
21 U.S.C. 823(g) 34, 49
21 U.S.C. 824(a)(4) 2, 46

Statutes and regulations—Continued: Page

21 U.S.C. 828(a) 4
21 U.S.C. 828(e) 16
21 U.S.C. 829 3
21 U.S.C. 829(a) 3, 16, 17
21 U.S.C. 829(b) 16, 17
21 U.S.C. 829(c) 16
21 U.S.C. 830(b)(3) 17
21 U.S.C. 830(b)(3)(A)(ii) 5, 18
21 U.S.C. 830(b)(3)(D)(iv) 17
21 U.S.C. 841(a) 2, 15, 26
21 U.S.C. 841(a)(1) 3, 15
21 U.S.C. 844(a) 15
21 U.S.C. 871(b) 4
21 U.S.C. 877 9
21 U.S.C. 903 ..... 4, 27
Harrison Act of 1914, ch. 1, 38 Stat. 785 19
Indian Child Welfare Act, 25 U.S.C. 1911(a) 25
Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-201, 88 Stat. 124 34
National Motor Vehicle Theft Act, 18 U.S.C. 2312 25
Revenue Act of 1932, ch. 209, § 504(b), 47 Stat. 247 25
Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(10) 25
21 U.S.C. 321(g)(1) 45
21 U.S.C. 321(g)(1)(B) 45
21 U.S.C. 352(j) (2000 & Supp. II 2002) 42
21 U.S.C. 355(d) 42
21 U.S.C. 355(i) (2000 & Supp. II 2002) 3
42 U.S.C. 257a (1970) 32, 33, 47
42 U.S.C. 290bb-2a (2000) 32, 33, 47, 48
42 U.S.C. 1320c-5(a)(1) 42
42 U.S.C. 1320c-5(b) 42
42 U.S.C. 1395y(a)(1)(A) (2000 & Supp. I 2001) 43
Cal. Health & Safety Code Ann. § 11362.5(B)(1)(A) (West 2004 Supp.) 28
Md. Code Crim. Law § 3-102 (Michie 2002) 22

Statutes and regulations—Continued: Page

Ohio Rev. Code Ann. § 3795.02 (Page 2003 Supp.) 22
Oregon Death with Dignity Act, Or. Rev. Stat. (2003):
§§ 127.800-127.995 ..... 1, 5
§ 127.800 6
§ 127.800(11) 6
§ 127.815 6
§ 127.815(d) 6
§ 127.820 6
§ 127.885(1) 6
§ 127.897 6
Or. Rev. Stat. § 163.125(1)(b) (2003) 6, 22, 44
S.C. Code Ann. § 16-3-1090 (2003) 22
Va. Code Ann. § § 8.01-622.1 (Michie 2000) 22
W. Va. Code § 16-30-15 (Michie 2001) 22
2005 Wyo. Sess. Laws Ch. 161 (H.B. 107) 22
21 C.F.R.:
Section 306.04(a) 4, 50
Section 1306.04 ..... 1, 4, 11, 14, 18, 21, 50
Section 1306.04(a) 4, 5, 16, 17, 18, 19, 24, 29
Section 1308.12(e) 29
28 C.F.R. 0.1009(b) 4

Miscellaneous:

American Med. Ass'n, *Current Opinions of the Council of Ethical and Judicial Affairs*, Opinion No. E-2.211 *Physicians-Assisted Suicide* <http://www.ama-assn.org/ama/pub/category/print/8459.html> 23
Assisted Suicide in the United States: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong., 2d Sess. (1996) 20
Center for Medicare & Medicaid Services, *Medicare Benefit Policy Manual* (2003) <http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp> 8, 24, 47

Miscellaneous—Continued: Page

130 Cong. Rec. (1984):
p. 1586 34
p. 25,849 34
p. 25,850 35
p. 25,851 ..... 34, 35
36 Fed. Reg. 7799 (1971) 4
38 Fed. Reg. 26,609 (1973) 4
51 Fed. Reg. (1986):
p. 17,476 30
p. 17,477 30
64 Fed. Reg. 35,928-35,930 (1979) 30
66 Fed. Reg. 56,607 (2001) 8
H.R. Rep. No. 1444, 91st Cong., 2d Sess. (1970) 2, 27, 32, 33, 34, 45, 48
H.R. Rep. No. 884, 93d Cong., 2d Sess (1974) 34, 48
Kevin F. O'Malley et al., *Federal Jury Practice and Instructions* (5th ed. 2000) 32
Kurt Hohenstein, *Just What the Doctor Ordered: The Harrison Anti-Narcotic Act, the Supreme Court and the Federal Regulation of Medical Practice, 1915-1919*, 26 J. Sup. Ct. Hist. 231 (2001) 33
New York State Task Force on Life and the Law, *When Death in Sought: Assisted Suicide and Euthanasia in the Medical Context* (May 1994) 23
9 *Oxford English Dictionary* (2d ed. 1989) 19
S. Rep. No. 225, 98th Cong., 1st Sess. (1983) 34
The Random House Dictionary of the English Language (2d ed. 1987) 18
Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 Wis. L. Rev. 1193 36
Jon R. Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 LePaul L. Rev. 408 (1968-1969) 36
Webster's Third New International Dictionary (1986) 19

In the Supreme Court of the United States

No. 04-623

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-63a) is reported at 368 F.3d 1118. The order of the district court granting respondents' motion for summary judgment (Pet. App. 64a-97a) is reported at 192 F. Supp. 2d 1077.

JURISDICTION

The judgment of the court of appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004 (Pet. App. 98a-99a). The petition for a writ of certiorari was filed on November 9, 2004, and was granted on February 22, 2005. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and the implementing regulation, 21 C.F.R. 1306.04, are set forth in the appendix to the petition. Pet. App. 149a-161a. Relevant provisions of the Oregon Death With Dignity Act, Or. Rev. Stat. §§ 127.800-127.995

(2003), are also set forth in the appendix to the petition. Pet. App. 162a-165a.

STATEMENT

1. a. The Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, was enacted in 1970 to provide stronger federal controls over drugs and other substances that are susceptible to abuse. Comprehensive Drug Abuse Prevention and Control (Controlled Substances) Act of 1970, preamble, 84 Stat. 1236; H.R. Rep. No. 1444, 91st Cong., 2d Sess. 1 (1970) (House Report). The CSA establishes a federal scheme that comprehensively regulates the manufacture, distribution, and possession of controlled substances. The CSA thus makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1).[1]

To dispense controlled substances lawfully, a physician or other practitioner must "obtain from the Attorney General a registration." 21 U.S.C. 822(a)(2). The CSA authorizes the Attorney General to deny or revoke the registration of a practitioner "if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f); accord 21 U.S.C. 824(a)(4). In determining the "public interest" for registration purposes, the Attorney General considers a number of factors, including the registrant's compliance with federal, state, and local laws relating to controlled substances and "such other conduct which may threaten the public health and safety." 21 U.S.C. 823(f).

Registered physicians or other practitioners may dispense controlled substances only "in the course of professional practice or research," 21 U.S.C. 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," 21 U.S.C. 822(b). A physician who dispenses controlled substances outside the "accepted limits" of medical practice is subject to prosecution under 21 U.S.C. 841(a)(1). *United States* v. *Moore*, 423 U.S. 122, 142 (1975).

[1] Under the CSA, the term "dispense" includes the issuance of a prescription by a practitioner as well as delivering a controlled substance directly to a patient. 21 U.S.C. 802(10).

Under the CSA, each controlled substance is placed on one of five schedules, depending on whether the substance has a currently accepted medical use in treatment in the United States, the relative abuse potential of the substance, and the extent to which abuse of the substance may lead to physical or psychological dependence. 21 U.S.C. 812. The Act imposes varying regulatory restrictions on controlled substances depending on the applicable schedule. Substances in schedule I—the most restricted schedule—have "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1). Human consumption of schedule I controlled substances is permissible only in a research setting where the research has been approved by the Food and Drug Administration (FDA) and the researcher has obtained from the Drug Enforcement Administration (DEA) a registration authorizing the specific research protocol. 21 U.S.C. 355(i) (2000 & Supp. II 2002), 823(f); see *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 491 (2001). By contrast, substances in schedules II through V have a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B), and therefore may be dispensed for medical use. 21 U.S.C. 829. With narrow exceptions not relevant here, substances in schedules II, III, and IV may be dispensed only pursuant to the "prescription of a practitioner." 21 U.S.C. 829(a) and (b).

When the CSA was enacted in 1970, Congress made an initial assignment of controlled substances to the schedules it

believed appropriate. 21 U.S.C. 812(c). Congress authorized the Attorney General, in consultation with the Secretary of Health and Human Services, to add or remove substances or to transfer substances from one schedule to another based upon statutory criteria that take into account changes in medical and scientific understanding and shifts in patterns of abuse. 21 U.S.C. 811, 812. In addition, Congress provided the Attorney General with broad authority to promulgate "rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. 821, and "any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the Act, 21 U.S.C. 871(b); see 21 U.S.C. 828(a) (making it "unlawful for any person to distribute" certain controlled substances except pursuant to an order form issued by the Attorney General in accordance with "regulations prescribed by him"). The Attorney General has delegated his functions under the Act to the Administrator of the DEA. 28 C.F.R. 0.100(b).

States remain free to enact their own laws relating to controlled substances, such as their own criminal penalties, but state laws are preempted to the extent of any "positive conflict" between a provision of state law and the CSA such that the two "cannot consistently stand together." 21 U.S.C. 903.

b. When the CSA became effective in 1971, DEA's predecessor (the Bureau of Narcotics and Dangerous Drugs) issued regulations to implement the Act through notice-and-comment rulemaking. One of those regulations, now found at 21 C.F.R. 1306.04(a),[2] requires that in order "to be effective," a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." A "purported prescription" that is not issued "in the usual course of professional treatment or in legitimate and authorized research" does not qualify as a "prescription within the meaning * * * of * * * 21 U.S.C. 829," and, if issued knowingly, will subject the practitioner "to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. 1306.04(a).

[2] This regulation was initially codified at 21 C.F.R. 306.04(a), see 36 Fed. Reg. 7799 (1971), and subsequently recodified at 21 C.F.R. 1306.04, see 38 Fed. Reg. 26,609 (1973).

As this Court noted in *Moore*, the requirement that a controlled substance be prescribed for a legitimate medical purpose may be implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is, in any event, made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See *Moore*, 423 U.S. at 137-139 & n.13. Essentially the same requirement flows from the fact that a physician issuing a prescription under the CSA must act "in the course of professional practice or research." 21 U.S.C. 802(21); accord 21 U.S.C. 844(a) (forbidding possession of controlled substances except "pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice"). Certain reporting requirements imposed by the CSA similarly define a "valid prescription" as one "issued for a legitimate medical purpose by an individual practitioner * * * acting in the usual course of the practitioner's professional practice." 21 U.S.C. 830(b)(3)(A)(ii). Indeed, a central condition for the lawful manufacture, distribution, or dispensing of a substance under schedules II through V is that the substance "has a currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B), and (5)(B).

2. In November 1994, Oregon voters passed a ballot initiative referred to as the Oregon Death with Dignity Act (DWDA), Or. Rev. Stat. §§ 127.800-127.995 (2003). The DWDA allows, as a matter of Oregon law, the prescribing and dispensing of "medication" for the purpose of enabling

an individual with a terminal disease to commit suicide. *Id.* §§ 127.800(11), 127.897. It requires the physician prescribing or dispensing the lethal substance to ensure that the patient is a resident of Oregon, is competent, has a terminal disease with less than six months of life-expectancy, and is making a voluntary and informed decision to obtain the substance for the purpose of ending his or her life. See *id.* §§ 127.800, 127.815. A second physician must also verify most of those facts. *Id.* §§ 127.815(d), 127.820. The DWDA provides that a physician who prescribes or dispenses a lethal amount or combination of drugs in accordance with the DWDA shall not "be subject to civil or criminal liability or professional disciplinary action" for doing so. *Id.* § 127.885(1). The DWDA thus "exempt[s] physicians who comply [with the DWDA's requirements] * * * from prosecution under [Or. Rev. Stat. § 163.125(1)(b)]," which otherwise makes it a crime under Oregon law for anyone, including a physician, to aid a suicide. *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994). Oregon is the only State in the Union that purports to authorize physician-assisted suicide.

3. In 2001, the Attorney General sought an opinion from the Office of Legal Counsel (OLC) in the Department of Justice on the question whether prescribing drugs for the purpose of assisting in a person's suicide, as contemplated in Oregon's DWDA, would constitute a valid prescription pursuant to the CSA and its implementing regulations. On June 27, 2001, OLC issued a memorandum concluding that "assisting in suicide is not a 'legitimate medical purpose' that would justify a physician's dispensing controlled substances consistent with the CSA." Pet. App. 130a; see *id.* at 106a-148a.[3]

[3] No interpretive rule had previously been issued by the Attorney General on this subject. As OLC noted in its memorandum to the Attorney General, the Administrator of the DEA had previously responded to a query from the Chairman of the House of Representatives Committee on the Judiciary by stating that assisting suicide in accordance with the DWDA would violate the CSA, see Pet. App. 108a & n.5, but then-Attorney General Janet Reno indicated a different conclusion in a subsequent letter to the Committee Chairman, see *id.* at 109a & n.7; Patients' Br. in Opp. 50a. Neither of those letters was published in the Federal Register.

The OLC memorandum explained that "[t]he CSA establishes a uniform, nation-wide statutory scheme for regulating the distribution of controlled substances," Pet. App. 130a, and noted that this Court had held, in *Oakland Cannabis*, that a California voter initiative purporting to recognize a medical use for marijuana as a matter of California law could not provide the basis for an implied "medical necessity" exception or defense in the CSA in the face of Congress's placement of marijuana in schedule I, which is for substances with "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B). Pet. App. 131a-133a. The OLC memorandum concluded that Oregon's ballot initiative likewise could not immunize a physician from federal prosecution or loss of registration under the CSA, if the Attorney General determined, pursuant to the regulatory authority granted to him in the CSA, that assisting an individual to commit suicide does not constitute a "legitimate medical purpose" for which controlled substances can be prescribed. *Id.* at 133a-134a.

The OLC memorandum also canvassed the views of medical and nursing associations, federal and state law, and judicial opinions and concluded, based on that review, that despite the Oregon voters' approval, physician-assisted suicide is not a "legitimate medical purpose." Pet. App. 114a. The memorandum explained that "state law and policy, with the sole exception of Oregon's, emphatically oppose assisted suicide," *id.* at 117a, and that federal law likewise prohibits such conduct in federal medical facilities and denies federal financial assistance in support of it, *id.* at 119a-122a. For example, the memorandum noted that the Health Care Financing

Administration in the Department of Health and Human Services had determined that physician-assisted suicide is not eligible for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." *Id.* at 121a (internal quotation marks omitted).[4] In addition, the OLC memorandum reviewed the position of leading organizations of the medical profession, including the American Medical Association, American Nurses Association, and American Psychiatric Association, all of which took the view that physician-assisted suicide was "fundamentally incompatible with the physician's role as healer." *Id.* at 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)).

On November 9, 2001, the Attorney General published an interpretive rule in the Federal Register (66 Fed. Reg. 56,607) that adopted the analysis of the OLC Memorandum. Pet. App. 100a-105a. The Attorney General determined that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR § 1306.04," and therefore that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." *Id.* at 102a. The Attorney General made clear that those conclusions "appl[y] regardless of whether state law authorizes or permits such conduct by practitioners or others." *Ibid.*[5]

4. The State of Oregon and others challenged the Attorney General's interpretive rule in the United States District

[4] The Health Care Financing Administration is now called the Centers for Medicare and Medicaid Services (CMS). CMS maintains this policy at present, and it is currently reflected in the *Medicare Benefit Policy Manual* ch. 16, § 20 (2003) <http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp>.

[5] The Attorney General distinguished assisted suicide from pain management and made clear that the latter, including "providing sufficient dosages of pain medication necessary to eliminate or alleviate pain," "has long been recognized as a legitimate medical purpose justifying physicians' dispensing of controlled substances." Pet. App. 103a.

Court for the District of Oregon. That court held the interpretive rule invalid and enjoined its application. Pet. App. 64a-97a. The federal parties appealed.

The court of appeals first held that the district court had lacked jurisdiction over respondents' suit. *Id.* at 2a-3a & n.1, 56a-61a. However, the court of appeals treated the action as a petition for review under 21 U.S.C. 877 that had been mistakenly filed in district court and transferred to the court of appeals. Pet. App. 2a-3a & n.1, 56a-61a. The court noted that there was a question whether any parties other than the health care practitioner parties had standing to challenge the Attorney General's interpretive ruling. *Id.* at 3a & n.2. In light of its determination that the practitioners could properly challenge the rule, the court of appeals declined to address whether the State of Oregon or patients also had standing. *Ibid.* On the merits, a divided panel granted the petitions for review.

a. The majority concluded that the interpretive rule was invalid absent an "unmistakably clear" indication of congressional intent to regulate physician-assisted suicide, because, in the majority's view, the rule "invokes the outer limits of Congress' power" by altering "the usual constitutional balance between the States and the Federal Government." Pet. App. 12a-13a (quoting *Solid Waste Agency* v. *United States Army Corps. of Eng'rs*, 531 U.S. 159, 172-173 (2001), and *Gregory* v. *Ashcroft*, 501 U.S. 452, 461 (1991) (citations and internal quotation marks omitted)). The court also held that the interpretive rule violates "the plain language of the CSA," *id.* at 13a, which, according to the majority, (1) only addresses "drug abuse," *id.* at 13a-14a, (2) establishes a principle of non-preemption, *id.* at 14a, (3) entrusts medical decisions to the Secretary of Health and Human Services (not the Attorney General), *id.* at 15a, and (4) requires the Attorney General to address all five statutory factors in 21 U.S.C. 823(f), including, in particular, whether the physician's con-

duct complies with state law, before adopting an interpretive rule that would affect physician registration under the CSA, Pet. App. at 16a. The court also found that the Attorney General's interpretive ruling, which it had already held to exceed the scope of his statutory authority, was not entitled to deference. *Id.* at 21a-23a. The panel therefore granted the petitions for review and "continued" the district court's injunction. *Id.* at 25a.

b. Senior Judge Wallace dissented. Pet. App. 25a-63a. He noted the presumption that Congress does not make the application of federal statutes dependent on state law, *id.* at 36a (citing *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989)), and observed that, while a physician's compliance with state law is relevant under the CSA in determining whether his or her registration would be consistent with the public interest, *id.* at 37a (citing 21 U.S.C. 823(f)(3) and (4)), other factors, including whether the physician's conduct "may threaten the public health and safety," are not dependent on state law, *ibid.* (citing 21 U.S.C. 823(f)(5)). The dissent further noted that, while the Secretary of Health and Human Services is specifically delegated certain functions under the CSA, responsibility under the Act for determining whether a physician's registration is consistent with the public interest is assigned to the Attorney General alone. *Id.* at 39a-40a.

Judge Wallace also rejected the majority's suggestion that application of the CSA to the dispensing of controlled substances to assist suicide is at the limits of Congress's power or would alter federal-state relations. Pet. App. 45a. He noted, rather, that Congress's authority under the Commerce Clause to regulate the distribution of controlled substances is well established. *Id.* at 49a-50a. Finally, the dissent observed that the Attorney General's conclusion that physician-assisted suicide is not a legitimate medical purpose

is well supported by an "overwhelming historical, legal, and medical consensus." *Id.* at 56a.

c. The court of appeals denied the government's petition for rehearing and rehearing en banc. Pet. App. 98a-99a.

SUMMARY OF ARGUMENT

The court of appeals acknowledged that the Controlled Substances Act prohibits practitioners from prescribing or dispensing controlled substances except for a "legitimate medical purpose" and "in the usual course of professional treatment." Pet. App. 5a (quoting 21 C.F.R. 1306.04). Respondents nonetheless seek to overturn the Attorney General's determination that the prescription of controlled substances, not for ordinary treatment, but for the express purpose of ending an individual's life, does not constitute a legitimate medical purpose or treatment under federal law. Respondents essentially submit that the Attorney General's interpretation of federal law would frustrate the purposes of a state-law voter initiative, and so the federal law must yield. Thus, the issue presented in this case is "who gets to decide," *id.* at 9a, whether a practitioner's conduct comports with this requirement of *federal law*—the Attorney General, pursuant to a uniform national standard, or each of the 50 States, according to 50 different views regarding the proper use of controlled substances. The text and structure of the CSA, as well as general principles of federalism, make clear that the Attorney General's interpretation of federal law need not yield to Oregon's contrary policy choices.

It is well established that the federal government, rather than the States, normally defines the terms in federal laws, giving them a single, nationwide definition. See *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30 (1989). There is no basis to depart from this general rule in interpreting the terms "legitimate medical purpose" and "treatment" in the context of the CSA. To the contrary, it is clear that Congress intended the CSA to set uniform nationwide

minimum standards for controlled substances, and, in light of the centrality of the "legitimate medical purpose" and "treatment" limitations to the entire federal scheme, those terms must also be given a uniform federal meaning.

Indeed, decisions of this Court already recognize that the CSA establishes national rules that do not yield to contrary medical policy that an individual State might seek to follow as a matter of state law. In *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), the Court made clear that the federal determination that marijuana has no "accepted medical use in treatment in the United States" foreclosed the assertion of a "medical necessity" defense to a federal prosecution under the CSA, despite a California law purporting to recognize a valid medical use of marijuana and to permit its use in certain circumstances.

There is no reason to believe that a different result is required when federal law determines that a drug has *a* legitimate medical purpose, but that not all uses of that drug are legitimate. This Court, for example, upheld a CSA conviction based on a physician's prescription of a schedule II drug—one that has a recognized and accepted medical use—for illegitimate purposes and did so on the basis of a national standard for medical practice. See *United States* v. *Moore*, 423 U.S. 122 (1975).

The conclusion that the Attorney General reached on this issue—that assisting suicide is *not* a legitimate medical purpose—finds overwhelming support in tradition, history, law, and medical expertise. The Attorney General's conclusion is consistent with the laws of 49 States, other laws and policies of the federal government, and leading associations of the medical profession. These facts alone demonstrate that the Attorney General's conclusion is reasonable and therefore must be upheld in light of the deference to which his views are entitled.

In the decision below, the court of appeals majority ignored the *Mississippi Band* line of cases, and declined to follow *Oakland Cannabis* and *Moore* in upholding the uniform national scope of the CSA. The court concluded that in order for the federal government to regulate controlled substances in a way that limits the practice of medicine in Oregon, a clear Congressional statement of its intent to do so was necessary. Pet. App. 11a. Citing *Gregory* v. *Ashcroft*, 501 U.S. 452, 460 (1991), the court of appeals held that a clear statement is necessary whenever federal law impacts upon an area within the traditional regulatory authority of the States, such as the practice of medicine. Pet. App. 11a. But *Gregory* applies only to federal laws that have an impact upon essential aspects of State sovereignty, such as the tenure of judges and location of a State's Capital. To expand *Gregory* to all areas of private conduct traditionally regulated by the States, as the court of appeals did here, would dramatically expand the clear statement requirement to encompass virtually all areas of federal regulation, in light of the breadth of the States' traditional police powers. The *Lochner*-era authority that the court of appeals cited for the proposition that certain categories of activity are presumptively beyond the authority of the federal government has long ago been rejected by this Court as both unworkable and unfounded, and there is no basis for resurrecting it now.

The court of appeals' belief that the Attorney General's ruling implicates the presumption against preemption, Pet. App. 14a-15a, was similarly misplaced. It is not "preemption" for the federal government to prohibit conduct as a matter of federal law that a particular State would deem permissible under its own laws. Oregon is free to decriminalize assisted suicide as a matter of Oregon law, as it has done. But Oregon could not displace contrary federal law by prefacing its state statutes with the phrase "notwithstanding any provision of federal law," and no presumption against

preemption allows it to exempt its physicians from compliance with federal directives sub silentio. Federal law does not yield even when it frustrates the purposes of state law.

There is no basis in the statutory language or purpose of the CSA for subordinating the Attorney General's ability to administer the Act's comprehensive national scheme for controlling dangerous substances to the views of each of the States regarding those substances' permissible uses.

ARGUMENT

I. THE CONTROLLED SUBSTANCES ACT ESTABLISHES A COMPREHENSIVE AND UNIFORM NATIONAL SYSTEM FOR REGULATING CONTROLLED SUBSTANCES, AND THE ATTORNEY GENERAL'S INTERPRETIVE RULING IMPLEMENTING THE ACT IS SUPPORTED BY THE OVERWHELMING WEIGHT OF AUTHORITY

A. The Prohibition On Dispensing Controlled Substances For Other Than A "Legitimate Medical Purpose" In The "Usual Course Of Professional Treatment" Is Central To The Regulatory Scheme Established By The Controlled Substances Act

The CSA prohibits a practitioner from prescribing controlled substances except "for a legitimate medical purpose" and "in the usual course of professional treatment." Pet. App. 5a (quoting 21 C.F.R. 1306.04). Those limitations appear throughout the CSA, reflecting their centrality to the comprehensive national scheme Congress established to regulate controlled substances. The starting point of the Act (indeed, its first provision) is the recognition that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. 801(1). And the entire federal scheme for regulating controlled substances is built upon the dual principles that the dispensing of controlled substances should be allowed for

such "legitimate medical purpose[s]," but that their distribution for illegitimate purposes should be prohibited. *Ibid.*

The Attorney General is charged under the CSA, 21 U.S.C. 811(a), with assigning controlled substances to the appropriate "schedule" according to whether they have a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b), and other factors. A substance for which the Attorney General has determined there is "no currently accepted medical use in treatment in the United States" is placed in schedule I, 21 U.S.C. 812(b)(1)(B), and may not be prescribed or dispensed except pursuant to a research protocol specifically approved by the Attorney General and the Secretary of Health and Human Services to ensure the substance will not be diverted from "legitimate medical or scientific use," 21 U.S.C. 823(f). Substances in other schedules may be dispensed by practitioners only because they have "a currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B), and (5)(B), thereby underscoring the centrality of "medical use" in "treatment" as a necessary condition for allowing a scheduled substance to be dispensed at all.

Other provisions of the Act similarly confine a practitioner's latitude in dispensing drugs in schedules II through V to legitimate medical uses in the course of treatment. The CSA makes it unlawful for "any person" to "dispense" a controlled substance "[e]xcept as authorized" by the CSA. 21 U.S.C. 841(a) and (a)(1). The Act defines "dispense" to include the "prescribing" of a controlled substance by a "practitioner," 21 U.S.C. 802(10), and defines "practitioner" to include a professionally-licensed physician dispensing controlled substances "in the course of professional practice," 21 U.S.C. 802(21). The CSA reiterates the "in the course of * * * professional practice" limitation in other provisions concerning the misuse of federal order forms, 21 U.S.C. 828(e), and unlawful possession of controlled substances, 21 U.S.C.

844(a). The "legitimate medical purpose" requirement is also reiterated in 21 U.S.C. 823(a)(1), which requires the Attorney General to ensure that there is an "adequate * * * supply" of schedule I and schedule II substances "for legitimate medical, scientific, research, and industrial purposes."

Consistent with those various provisions of the Act, the Attorney General's regulation confirms that a prescription for a controlled substance "must be issued for a legitimate medical purpose" and that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription" within the meaning of the CSA. 21 C.F.R. 1306.04(a).

This Court has similarly recognized and enforced the CSA's prohibition on the prescription of controlled substances for other than legitimate medical purposes. In *United States* v. *Moore*, 423 U.S. 122 (1975), the Court unanimously held that physicians violate the CSA "when their activities fall outside the usual course of professional practice." *Id.* at 124; see *id.* at 141-142 ("provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits"). In so holding, the Court noted that "[t]he medical purpose requirement," which is explicit in 21 U.S.C. 829(c), could be implicit in 21 U.S.C. 829(a) and (b) and is, in any event, made explicit with respect to those provision by the Attorney General's regulation, now codified at 21 C.F.R. 1306.04(a). 423 U.S. at 137 n.13. Following *Moore*, the courts of appeals have consistently applied a "legitimate medical purpose" standard in CSA prosecutions of physicians and pharmacists. See, *e.g.*, *United States* v. *Daniel*, 3 F.3d 775, 778 (4th Cir. 1993), cert. denied, 510 U.S. 1130 (1994); *United States* v. *Kaplan*, 895 F.2d 618, 619 (9th Cir. 1990); *United States* v. *Jamieson*, 806 F.2d 949, 951 (10th Cir. 1986); *United States* v. *Chin*, 795

F.2d 496, 503 (5th Cir. 1986); *United States* v. *Hammond*, 781 F.2d 1536, 1537 (11th Cir. 1986); *United States* v. *Plesons*, 560 F.2d 890, 896-897 & n.6 (8th Cir. 1977); accord *United States* v. *Hughes*, 895 F.2d 1135, 1143 (6th Cir. 1990) ("legitimate medical practice").[6]

In fact, Congress has adopted a statutory definition of "valid prescription" that mirrors the Attorney General's. In 2000, Congress revised the reporting requirements for distributions of certain listed chemicals. See Children's Health Act of 2000, Pub. L. No. 106-310, Tit. XXXVI, Div. B, § 3652, 114 Stat. 1239 (21 U.S.C. 830(b)(3)). In so doing, Congress exempted from the reporting requirements "[d]istributions * * * pursuant to a valid prescription." 21 U.S.C. 830(b)(3)(D)(iv). Congress defined the phrase "valid prescription" in terms almost identical to those used by the Attorney General regarding the requirement for a "prescription" under 21 U.S.C. 829(a) and (b), as one "issued for a legitimate medical purpose by an individual practitioner * * *

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[6] The phrases "legitimate medical purpose," 21 C.F.R. 1306.04(a), and "in the course of professional practice," 21 U.S.C. 802(21), both reflect a concern for allowing only legitimate or professionally appropriate uses of controlled substances and reflect essentially the same standard. See, *e.g.*, *Daniel*, 3 F.3d at 778 (allegation that drug distributions were not "for a legitimate medical purpose" was sufficient to allege that they fell "outside the boundaries of the registrant's professional practice"); *United States* v. *Kirk*, 584 F.2d 773, 784 (6th Cir.) ("[T]here is no difference in the meanings of the statutory phrase, 'In the usual course of professional practice' and the regulations' phrase, 'legitimate medical purpose.'"), cert. denied, 439 U.S. 1048 (1978); *Plesons*, 560 F.2d at 897 n.6 (same); *United States* v. *Rosenberg*, 515 F.2d 190, 196-197 (9th Cir.) (phrases "not 'in the usual course of professional practice' and not 'for any legitimate medical or research purposes'" "have essentially the same meaning"), cert. denied, 423 U.S. 1031 (1975); *United States* v. *Nelson*, 383 F.3d 1227, 1231 (10th Cir. 2004) (noting that "there is considerable room to doubt" whether the phrases "outside the usual course of medical practice" and "without legitimate medical purpose" have different meanings). Cf. *United States* v. *Tran Trong Cuong*, 18 F.3d 1132, 1138 (4th Cir. 1994) (stating the "legitimate medical purpose" standard is, if anything, more favorable to the defendant than the standard stated in *Moore*).

acting in the usual course of the practitioner's professional practice," 21 U.S.C. 830(b)(3)(A)(ii).

B. The Attorney General's Conclusion That Facilitating An Individual's Suicide Is Not A "Legitimate Medical Purpose" In "Treatment" For Purposes Of The Controlled Substances Act Is Supported By The Overwhelming Weight Of Authority

The overwhelming weight of authority supports the Attorney General's conclusion that dispensing drugs for the purpose of hastening a person's death is outside "the usual course of professional treatment" and not a "legitimate medical purpose" under the federal regulatory scheme. 21 C.F.R. 1306.04. The Attorney General's conclusion is supported by the ordinary meaning of the CSA's text and by centuries of almost uniform opposition to the practice of assisted suicide, including the current opposition of leading medical societies, federal law, and the law of 49 of the 50 States. In light of the deference owed to the Attorney General's construction of the CSA, this broad consensus amply supports the reasonableness of his conclusion.

1. The language of the CSA demonstrates that Congress did not authorize physicians to prescribe controlled substances for the purpose of ending their patients' lives

As explained above, the operative requirements for a "prescription" to be valid under the CSA are that it be issued for a "legitimate medical purpose" and "in the usual course of professional treatment." 21 C.F.R. 1306.04(a). See 21 U.S.C. 830(b)(3)(A)(ii). Because the CSA and implementing regulations do not specifically define those terms, they should be given their "ordinary meaning." See, *e.g.*, *Asgrow Seed Co.* v. *Winterboer*, 513 U.S. 179, 187 (1995); *FDIC* v. *Meyer*, 510 U.S. 471, 476 (1994). The ordinary meaning of the term "medical" is "[p]ertaining or related to the healing art or * * * to 'medicine,'" 9 *Oxford English*

Dictionary 546 (2d ed. 1989), and the term "medicine" refers to "[t]hat department of knowledge and practice which is concerned with the cure, alleviation, and prevention of disease in human beings, and with the restoration and preservation of health," *id.* at 549; see *Webster's Third New International Dictionary* 1402 (1966) ("the science and art dealing with the maintenance of health and the prevention, alleviation, or cure of disease"); *The Random House Dictionary of the English Language* 1194 (2d ed. 1987) ("the art or science of restoring or preserving health or due physical condition"). Whatever else the provision of controlled substances for the express purpose of hastening death may constitute, it clearly crosses a line and involves something other than the restoration or preservation of health, *i.e.*, involves something other than medicine. Indeed, in one of this Court's first decisions to construe the Harrison Act of 1914, ch. 1, 38 Stat. 785 (Harrison Act)—the precursor to the CSA—the Court held that the term "prescription" by itself plainly connoted a requirement that the physician be attempting to "treat[]" or "cure" an illness. See *Webb* v. *United States*, 249 U.S. 96, 99-100 (1919) (To call a doctor's order for morphine that was "not * * * issued * * * in the course of professional treatment in the attempted cure of the habit" "a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required."). Assisting an individual's suicide does not fit within the ordinary meaning of the phrases "legitimate medical purpose" or "usual course of professional treatment," 21 C.F.R. 1306.04(a), because it does not aim to preserve the patient's health or to cure, alleviate, prevent, or "treat" the disease or its symptoms in the patient. To the contrary, it aims to bring about the patient's death.

Moreover, the context within which these phrases are used within the CSA confirms that Congress intended them to be construed according to their ordinary usage. For ex-

ample, the legislative findings that accompany the CSA reflect that Congress associated "legitimate medical purpose" with "maintain[ing] the health and general welfare of the American people." 21 U.S.C. 801(1). Similarly, Congress's direction that controlled substances be scheduled according to whether they have a "currently accepted medical use *in treatment*" and an "accepted *safety* for use * * * under medical supervision," 21 U.S.C. 812(b) (emphasis added), reflects Congress's intent that physicians dispense controlled substances to preserve and enhance—not end—their patients' lives. It certainly makes no sense to talk about the "safety for use" of drugs when they are dispensed to end a person's life. "A doctor who assists a suicide * * * 'must, necessarily and indubitably, intend primarily that the patient be made dead.'" *Vacco* v. *Quill*, 521 U.S. 793, 802 (1997) (quoting *Assisted Suicide in the United States: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 104th Cong., 2d Sess. 367 (1996) (testimony of Dr. Leon R. Kass)). The CSA's repeated use of the word "medical" in conjunction with the words "treatment," "health," and "safety" confirms that suicide is not a "legitimate medical purpose" under the CSA, because any procedure intended to cause the death of a patient is not "treatment" and does not promote the patient's "health" or "safety."[7]

[7] The Attorney General's interpretive ruling distinguishes between a physician who intentionally brings about his patient's death and one who treats the pain associated with illness, even though such treatment may have the unintended consequence of hastening the patient's death. Pet. App. 103a. See *Vacco*, 521 U.S. at 802 (noting the significance of this distinction).

2. The Attorney General's interpretation of the phrases "legitimate medical purpose" and "professional treatment" to exclude physician-assisted suicide is supported by historical tradition and the near-unanimity of state and federal authority

Even if the provisions of the CSA were not themselves clear, deference is owed to the Attorney General's construction of the Act and the implementing regulation describing what constitutes a valid prescription for purposes of federal law. See *Chevron U.S.A. Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 843-844 (1984). The Attorney General, and his delegee the Administrator of the DEA, are, after all, the federal officers with primary responsibility for enforcing the CSA. See *Alliance for Cannabis Therapeutics* v. *DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991) ("neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable"); *Trawick* v. *DEA*, 861 F.2d 72, 75-76 (4th Cir. 1988) (deferring to DEA Administrator's determination that registrant's actions were inconsistent with the public interest and that his registration should be revoked). Indeed, the Attorney General's interpretation of his own regulation, 21 C.F.R. 1306.04, is entitled to particular deference under *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997), and *Thomas Jefferson University* v. *Shalala*, 512 U.S. 504, 512 (1994).

The Attorney General's conclusion—that the provision of drugs for the express purpose of ending life is something other than legitimate medical treatment—is consistent with the position adopted by 49 States, the federal government in other contexts, and leading associations of the medical profession. As the Court noted in *Washington* v. *Glucksberg*, 521 U.S. 702 (1997):

> In almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide. The States' assisted-suicide bans are not innovations. Rather, they are longstanding expressions of the States' commitment to the protection and preservation of all human life.

Id. at 710. See *id.* at 710 n.8 (citing compilation of state authorities); *id.* at 776 n.14 (Souter, J., concurring) (citing state statutes expressly prohibiting assisting a suicide).[8] The laws of all 49 states, apart from Oregon, express their disapproval in one form or another of assisted suicide. See *ibid.*; *Vacco*, 521 U.S. at 805-806 & n.9 (collecting health-care and living-will statutes of 49 States and two territories disapproving of suicide and assisted suicide). It is Oregon's physician-assisted suicide statute that is contrary to longstanding historical practices as well as to the contemporary state of the law. *Glucksberg*, 521 U.S. at 710-719; *id.* at 723 ("[W]e are confronted with a consistent and almost universal tradition that has long rejected [a right to physician-assisted suicide], and continues explicitly to reject it today, even for terminally ill, mentally competent adults.").[9] Oregon is free to change its state law; but doing so does not require the Attorney General to change his interpretation of federal law.

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[8] Since *Glucksberg* was decided, Maryland and South Carolina have passed statutes expressly prohibiting assisted suicide. See Md. Code, Crim. Law § 3-102 (Michie 2002); S.C. Code Ann. § 16-3-1090 (2003). In addition, West Virginia and Wyoming have adopted new statutes that expressly provide that laws permitting the withdraw of medical treatment do not authorize assisted suicide. See W. Va. Code § 16-30-15 (Michie 2001); 2005 Wyo. Laws ch. 161 (H.B. 107) (to be codified at Wyo. Stat. § 35-22-414(c)). Virginia and Ohio have passed statutes declaring their opposition to assisted suicide and authorizing their courts to enjoin the assistance of suicide. Va. Code Ann. § 8.01-622.1 (Michie 2000); Ohio Rev. Code Ann. § 3795.02 (Page 2003 Supp.).

[9] Indeed, Oregon as well criminalizes assisting another's suicide if done by anyone other than a physician acting pursuant to the DWDA. See Or. Rev. Stat. § 163.125(1)(b) (2003); *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994).

The Attorney General did not ignore the laws of the States in interpreting the CSA to bar the dispensing of controlled substances to facilitate suicide. To the contrary, his interpretation is consistent with the position of the overwhelming majority of the States. In light of the historical unanimity of opinion on this issue, and the fact that the CSA predated Oregon's DWDA by several decades, it is inconceivable that Congress, in enacting the CSA, regarded assisted suicide as a legitimate "medical" practice in the "treatment" of disease.

Numerous health care experts have likewise agreed that physician-assisted suicide is not a legitimate medical treatment. In *Glucksberg*, the Court noted that New York State's Task Force on Life and the Law—a group including doctors, ethicists, lawyers, religious leaders and interested laypersons—had unanimously concluded that "[l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable. . . . [T]he potential dangers of this dramatic change in public policy would outweigh any benefit that might be achieved." 521 U. S. at 719 (quoting New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 120 (May 1994)). Likewise, as OLC noted in the memorandum on which the Attorney General's interpretive ruling was based, the American Medical Association (AMA), American Nurses Association, and American Psychiatric Association filed a joint brief in *Glucksberg* taking the position that physician-assisted suicide is "fundamentally incompatible with the physician's role as healer." Pet. App. 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)); see *Glucksberg*, 521 U.S. at 731 (quoting same). The ethical guidelines of the AMA continue to state that "[p]hysician assisted suicide is fundamentally incompatible with the physician's role as healer." AMA, *Current Opinions of the*

Council of Ethical and Judicial Affairs, Opinion No. E-2.211, Physician-Assisted Suicide (last visited Apr. 28, 2005) <http://www.ama-assn.org/ama/pub/category/print/8459. html>.

In other federal laws and programs as well, physician-assisted suicide is not regarded as a legitimate medical practice. In 1997, Congress passed a broad ban on the federal funding of assisted suicide. See Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, § 3(a), 111 Stat. 23. Administratively, the Department of Health and Human Services's Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) similarly has determined that physician-assisted suicide is not eligible for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." Pet. App. 121a (internal quotation marks omitted); *Medicare Benefit Policy Manual* ch. 16, § 20 (2003).

There can be no question, then, that the Attorney General's interpretive ruling is consistent with the prevailing legal and medical views regarding medical practice and on that basis is, at the very least, a reasonable interpretation of federal law, which is entitled to deference.

C. The Controlled Substances Act Has A Uniform Meaning, Determined By Federal Law, Throughout The United States

As the court of appeals recognized, the principal question presented by this case is "who gets to decide," Pet. App. 9a, whether particular conduct comports with the federal requirement under the CSA that a prescription be issued for a "legitimate medical purpose" and in the "usual course of professional treatment," 21 C.F.R. 1306.04(a). Although Congress presumably could develop a statutory scheme that depended entirely on state law and varied across the Nation, it did not do so in the CSA. The text and structure of the CSA, as reinforced by general principles of federalism, make clear

that a uniform federal standard determines what constitutes a legitimate medical purpose under this federal statute.

1. *There is a presumption in favor of a uniform national standard.* It is a well-established principle of statutory construction that, "in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43, 47 (1989) (quoting *Jerome* v. *United States*, 318 U.S. 101, 104 (1943), and holding that the word "domicile" used in the Indian Child Welfare Act, 25 U.S.C. 1911(a), should have a uniform meaning rather than vary according to state law). Rather, "[b]ecause federal law applies nationally," the assumption is "that Congress desires national uniformity in the application of its laws." *Salt Lake Tribune Publ'g Co.* v. *Management Planning, Inc.*, 390 F.3d 684, 688 (10th Cir. 2004). Accordingly, this Court has repeatedly adopted uniform national definitions for the terms in federal laws and refused to make the definitions of those terms dependent upon the vagaries of state law. See, *e.g.*, *Reves* v. *Ernst & Young*, 494 U.S. 56, 71 (1990) (the meaning of the word "maturity" in the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(10), "is a question of federal law" and does not differ from State to State based on differences in state law); *United States* v. *Turley*, 352 U.S. 407 (1957) (same for the word "stolen" in the National Motor Vehicle Theft Act, 18 U.S.C. 2312); *United States* v. *Pelzer*, 312 U.S. 399 (1941) (same for the phrase "future interests" in the Revenue Act of 1932, ch. 209, § 504(b), 47 Stat. 247). Because nothing in either the CSA or its implementing regulations makes the definition of "legitimate medical purpose" or "treatment" depend upon state law, this Court's decisions in *Mississippi Band* and similar cases mandate that those phrases be given uniform federal definitions and not vary from State to State.

Indeed, the *Mississippi Band* presumption is particularly appropriate with respect to the CSA, which establishes a "comprehensive federal scheme" for regulating controlled substances. *Gooding* v. *United States*, 416 U.S. 430, 449 (1974). The CSA contains numerous provisions reflecting the need for uniform minimum federal standards. Congress emphasized that when employed for a "legitimate medical purpose," controlled substances are "necessary to maintain the health and general welfare of the American people," 21 U.S.C. 801(1), but that "illegal * * * distribution * * * and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. 801(2). And Congress specifically found that "*[f]ederal* control" of all incidents of the traffic in controlled substances, including intrastate incidents, is "essential to the effective control" of such substances. 21 U.S.C. 801(6) (emphasis added). Accordingly, the core provisions of the CSA prohibit the dispensing of controlled substances "[e]xcept as authorized *by this subchapter*," 21 U.S.C. 841(a) (emphasis added), and authorize registered physicians to prescribe controlled substances only "to the extent authorized by their registration and in conformity with the other provisions *of this subchapter*," 21 U.S.C. 822(b) (emphasis added). The repeated cross-references to the provisions of the CSA itself, without any comparable references to state law, demonstrate Congress's intent to create a comprehensive federal system of regulation.

Other provisions of the CSA confirm that the requirement of a legitimate "medical" purpose in "treatment" cannot be construed as a delegation to the States to determine what constitutes legitimate medical practices for purposes of the CSA. The CSA authorizes the Attorney General to assign controlled substances to particular schedules, 21 U.S.C. 811(a), depending on whether they have "accepted *medical use in treatment in the United States*," 21 U.S.C. 812(b) (emphasis added). The CSA's scheduling provisions plainly contemplate a single national determination of accepted "medical" use; there is no such thing as a controlled substance that appears in schedule I in those States that do not recognize any accepted "medical" use for the substance but appears in a different schedule in other States that do recognize such a use. Moreover, the fact that Congress itself initially put certain drugs on schedule I—subject to rescheduling based on the judgments of federal, not state, officials—is a particularly strong indication that the Congress that enacted the CSA believed medical judgments could and should be made on the national level. See pp. 28-30, *infra*.

2. *Judicial decisions interpreting the CSA confirm that it provides a uniform federal-law standard.* This Court's decisions confirm that the minimum standards established by the CSA for dispensing controlled substances are uniform throughout the Nation and are not subject to revision by the States.[10] As the Court has recognized, "the application of federal legislation is nationwide and at times the federal program would be impaired if state law were to control." *Dickerson* v. *New Banner Inst., Inc.*, 460 U.S. 103, 119-120 (1983). The determination whether a drug has a "currently accepted medical use in treatment in the United States," for purposes of scheduling the substance under 21 U.S.C. 812(b), is such an instance in which the need for federal uniformity precludes resort to 50 different state laws.

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[10] The fact that the CSA sets national minimum standards as a matter of federal law does not mean that it preempts the entire field of controlled substances regulation. It does not. See 21 U.S.C. 903; House Report 29. The CSA does expressly preempt state law when there is a "positive conflict between [a] provision of [the CSA] and [a] State law so that the two cannot consistently stand together." 21 U.S.C. 903. In that event, however, it is state law, not federal law, that must yield. The CSA clearly creates a uniform minimum federal regulation of controlled substances; States may relax or eliminate their own state regulatory schemes or impose stricter state limits on controlled substances, but they are not free to revise the uniform federal standard.

a. In *Oakland Cannabis*, for example, the Court considered a ballot initiative passed by California voters that established, for purposes of state law, that seriously ill Californians could "use marijuana for medical purposes." 532 U.S. at 486 (quoting Cal. Health & Safety Code Ann. § 11362.5(b)(1)(A) (West 2004 Supp.)). Nonetheless, this Court rejected a marijuana cooperative's reliance on the state law as supporting a "medical necessity" defense to a federal prosecution under the CSA. The Court held that such a defense would be inconsistent with Congress's finding, in classifying marijuana in schedule I, that the substance has "no currently accepted medical use in treatment in the United States." *Id.* at 492, see *id.* at 493 (notwithstanding the California law, "Congress has made a determination that marijuana has no medical benefits worthy of an exception," and neither the State nor the Court could "override a legislative determination" to that effect).

Although Congress, rather than the Attorney General, had made the initial determination that marijuana has no generally accepted medical use in treatment in the United States, that distinction makes no difference as to the determination's binding effect on the States. Indeed, the Court expressly rejected the converse argument—that Congressional determinations were entitled to less deference—in *Oakland Cannabis*, 532 U.S. at 492-493, and the CSA expressly grants the Attorney General authority to assign substances to the appropriate schedule, and to move substances (including those originally classified by Congress) among schedules. 21 U.S.C. 811(a).

b. Just as California's ballot initiative purporting to recognize, as a matter of state law, a permissible "use [for] marijuana for medical purposes," Cal. Health & Safety Code § 11362.5(b)(1)(A), did not compel recognition in *Oakland Cannabis* of an exception to the generally applicable federal rule under the CSA that a schedule I substance has no "generally accepted medical use in treatment in the United States," such a state law would not compel the Attorney General to *reclassify* marijuana to a different schedule under the CSA. Rather, such a reclassification requires an independent *federal* assessment of the medical and scientific evidence and, if supported by substantial evidence, would bind the entire Nation for purposes of the CSA. See *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131 (D.C. Cir. 1994) (upholding DEA's refusal to reschedule marijuana as supported by substantial evidence); see also *Gettman* v. *DEA*, 290 F.3d 430, 432 (D.C. Cir. 2002) (explaining CSA procedures for rescheduling a controlled substance). As the D.C. Circuit held in *Alliance for Cannabis*, "only rigorous scientific proof can satisfy the CSA's 'currently accepted medical use' requirement." 15 F.3d at 1137. There is no basis in the CSA for substituting a ballot initiative, such as California voters' approval of medical marijuana or Oregon voters' endorsement of physician-assisted suicide, for the "rigorous scientific proof" required by the CSA for a substance to be found to have an "accepted medical use." *Ibid.*

Nor is there any reason to conclude, as the court of appeals did in this case, that the Attorney General's determination whether a *particular* use of a controlled substance qualifies as a "legitimate medical purpose" "in the usual course of professional treatment" for CSA purposes, 21 C.F.R. 1306.04(a), is any less binding in the States than his determination whether a substance has *any* accepted medical use. *Oakland Cannabis* makes clear that the Attorney General could reclassify the schedule II substances typically used by Oregon physicians to assist suicide[11] to schedule I if the medical and scientific evidence warranted—despite Ore-

[11] According to the Oregon Department of Human Services, the three drugs that have been dispensed pursuant to the DWDA are secobarbital, pentobarbital, and amobarbital, all of which are schedule II depressants. See Patients' Br. in Opp. 29a-30a; 21 C.F.R. 1308.12(e).

gon's assisted suicide initiative. There is no reason he should have less authority to determine that, while those schedule II substances have *other* generally accepted medical uses in treatment, deliberately assisting a person to commit suicide is not one of them.

The Attorney General imposed just that type of limitation on the use of a schedule II substance when he transferred the substance dronabinol (which was approved by the FDA in a particular form marketed under the brand name Marinol) from schedule I to schedule II. Dronabinol is an isomer of tetrahydrocannabinols (THC), which is the principal psychoactive substance in marijuana. 51 Fed. Reg. 17,476 (1986). After the FDA determined that Marinol has a legitimate medical use in alleviating nausea associated with cancer treatment, *id.* at 17,477, DEA issued a rule transferring the substance from schedule I to schedule II—as a drug with "a currently accepted medical use with severe restrictions," 21 U.S.C. 812(b)(2)(B); 51 Fed. Reg. at 17,476. In so doing, however, DEA recognized the significant risk that Marinol would be dispensed by physicians for improper purposes, rather than the accepted use recognized by the FDA, and that practitioners might "attempt to justify illegal or improper distribution or dispensing by claiming unique knowledge of [the] drug's effectiveness for a broad range of medical indications." *Id.* at 17,477. For that reason, at the same time DEA moved Marinol to schedule II, it also made clear that a physician who dispenses Marinol "for medical indications outside the approved use associated with cancer treatment, except within the confines of a structured and recognized research program," would be subject to revocation of his or her registration and possible criminal prosecution. *Ibid.*[12]

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[12] DEA subsequently retransferred Marinol to schedule III under the CSA. See 64 Fed. Reg. 35,928-35,930 (1999). The Federal Register notice of the final rule moving Marinol to Schedule III noted that the FDA had expanded the indications for Marinol's use to include the treatment of anorexia associated with weight loss in patients with AIDS, but that notice did not expressly continue the prior policy statement concerning restrictions on prescribing Marinol.

c. This Court's decision in *Moore* also strongly supports the conclusion that the CSA establishes a uniform *federal* standard for the permissible dispensing of substances regulated under the Act. *Moore* involved the prosecution of a physician who prescribed large quantities of methadone tablets with little or no medical assessment or supervision. See 423 U.S. at 126. He was convicted under the CSA for prescribing controlled substances outside the usual course of professional practice. The Court held that the CSA was intended to limit a physician's distribution of controlled substances to actions "as a physician" and in the course of "professional practice." *Id.* at 140, 141.

The opinion in *Moore* makes clear that Moore's conviction, which the Court affirmed, was based on a uniform nationwide standard for determining the lawfulness of the prescriptions under the CSA: Whether the prescriptions were "in accordance with a standard of medical practice generally recognized and accepted *in the United States*." 423 U.S. at 139 (quoting jury instructions) (emphasis added). The Court recognized that one of Congress's objectives in replacing the Harrison Act with the CSA was precisely to establish clear and consistent federal "limits on free experimentation with drugs" by physicians, *id.* at 143, and to clarify that "physicians who go beyond approved practice," as determined by the Secretary of Health, Education and Welfare (now Health and Human Services) and the Attorney General, are subject to criminal prosecution, *id.* at 144. See *ibid.* (noting that the CSA "requires the Secretary * * *, after consultation with the Attorney General and national addict treatment organizations, to 'determine the appropriate methods of professional practice in the medical treatment of . . . narcotic ad-

dition'" (quoting 42 U.S.C. 257a (1970), recodified at 42 U.S.C. 290bb-2a (2000)), and that those federal officials would "clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients" (quoting House Report 14, 15)).

With the exception of the decision below, the courts of appeals have followed *Moore* and applied a national standard for professional practice under the CSA. See *United States* v. *Vamos*, 797 F.2d 1146, 1151, 1153 (2d Cir. 1986) (CSA incorporates the standard of professional practice "generally recognized and accepted in the United States"), cert. denied, 479 U.S. 1036 (1987); *United States* v. *Hayes*, 794 F.2d 1348, 1351-1352 (9th Cir. 1986) ("the standard of medical practice generally recognized in the country"), cert. denied, 479 U.S. 1086 (1987); *United States* v. *Norris*, 780 F.2d 1207, 1209 & n.2 (5th Cir. 1986) (same as *Vamos*); *United States* v. *Daniel*, 3 F.3d 775, 778 (4th Cir. 1993) (same), cert. denied, 510 U.S. 1130 (1994); Kevin F. O'Malley et al., *Federal Jury Practice and Instructions (Criminal)* § 64.16, at 428 (5th ed. 2000) (same). Indeed, several courts, including the court below, have specifically rejected arguments by practitioner-defendants that their federal-law obligations under the CSA should depend on state law. In *United States* v. *Rosenberg*, 515 F.2d 190, 198 (1975), the Ninth Circuit affirmed the conviction of a California doctor under the CSA and rejected as "singularly unpersuasive" his contention that "the determination of whether or not he was acting in the course of his professional practice must be determined by the state of California." Similarly, in *United States* v. *Leal*, 75 F.3d 219 (1996), the Sixth Circuit rejected a pharmacist's defense against prosecution for violating the CSA that state law imposed no duty to identify suspicious prescriptions. *Id.* at 226-227.[13] As the Sixth Circuit held, "[w]hether state law

[13] *Leal* was later overruled on other grounds. See *United States* v. *Kennedy*, 107 Fed. Appx. 518 (6th Cir. 2004).

imposes an equivalent civil or criminal duty is irrelevant" to whether the pharmacist had violated his "federal duty * * * to be vigilant in filling prescriptions." *Id.* at 227.

3. *The CSA's legislative history confirms that there is a uniform federal-law standard.* The CSA's legislative history reflects Congress's understanding that the Harrison Act, the predecessor to the CSA, created a federal standard for determining what constitutes a legitimate medical practice and its intent to clarify that *federal* standard, not to cloud that standard by overlaying potentially disparate state standards. The House Report noted that "for the last 50 years" physicians had been subject to federal prosecution under the Harrison Act if their "methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors of what constitutes appropriate methods of professional practice." House Report 15.[14] The House Report states an intent "to clarify for the medical profession in the United States the extent to which they may safely go in treating narcotic addicts as patients," *id.* at 14, and the CSA directed the Secretary, working together with the Attorney General, to do so, 42 U.S.C. 290bb-2a (2000) (formerly codified at 42 U.S.C. 257a (1970)). The House Report leaves no doubt that Congress intended to establish a uniform *federal* standard for the use of narcotics in medical treatment, rather than to confuse standards by incorporating varying

[14] Congress's understanding of the Harrison Act was clearly correct. "What ensued soon after passage of the act can fairly be described as the most comprehensive general criminal enforcement of any law against medical professionals in U.S. history." Kurt Hohenstein, *Just What the Doctor Ordered: The Harrison Anti-Narcotic Act, the Supreme Court, and the Federal Regulation of Medical Practice, 1915-1919*, 26 J. Sup. Ct. Hist. 231, 231-232 (2001). See, *e.g.*, *United States* v. *Webb*, 249 U.S. 96 (1919); *United States* v. *Doremus*, 249 U.S. 86 (1919).

state law duties. See House Report 14-15; *Moore*, 423 U.S. at 144 (discussing same).[15]

Moreover, in subsequent amendments to the CSA, Congress has diminished the relevance of state law in the one area where the Act refers to it. As originally enacted, the CSA incorporated state law only with respect to the standards for obtaining a registration. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 303(f), 84 Stat. 1253; *Moore*, 423 U.S. at 138 n.15 ("Registration was mandatory for practitioners with state licenses."). But Congress modified those standards in 1984 to allow the Attorney General to make practitioner registration determinations on independent federal grounds, see 21 U.S.C. 823(f) (making compliance with state law only one of several factors in determining whether the public interest would be served by registering a physician), precisely because States were not adequately regulating abuses by physicians of their prescription-writing authority. See, *e.g.*, S. Rep. No. 225, 98th Cong., 1st Sess. 262 (1983) (noting that it "may clearly be contrary to the public interest" to require the Attorney General to grant a practitioner's registration application to any practitioner licensed under state law); 130 Cong. Rec. 25,849 (1984) (statement of Rep. Fish) ("State laws regarding the dispensing of controlled substances are * * * inadequate."); *id.* at 1586 (statement of Sen. Laxalt) (Congress intended to "expand[] the standards for practitioner registration beyond the * * * exclusive reliance upon

[15] The parts of the 1970 Act specific to the treatment of narcotics addiction were superseded by the Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124. The 1974 law also prescribed specific and uniform federal standards with respect to the use of controlled substances in the treatment of narcotics addiction. It requires federal registration for narcotic treatment programs, 21 U.S.C. 823(g), which is "predicated on the demonstrated ability to comply with *medical standards established by the FDA and security standards established by DEA*," H.R. Rep. No. 884, 93d Cong., 2d Sess. 4 (1974) (emphasis added).

authorization by the practitioner's own jurisdiction"); see also *id.* at 25,850 (statement of Rep. Hughes) (drugs "prescribed by physicians * * * account for about 60 percent of the overdoses each year"); *id.* at 25,851 (statement of Rep. Gilman) (physician prescriptions are responsible for the diversion of "close to 1 million doses of dangerous drugs per year" from legitimate channels to illegitimate channels). Congress wanted to "make it easier" for DEA "to suspend or revoke the authority of physicians and pharmacists who write or dispense prescriptions in a way that is threatening to the public health or safety." *Ibid.* Thus, even where the CSA had incorporated state law by reference, Congress has revised the Act to make the federal regulation of controlled substances less dependent on the varying determinations of state authorities, and thereby even more uniformly applied throughout the Nation.

The court of appeals' ruling could have a significant adverse impact on federal prosecutions of physicians under the CSA outside the context of assisted suicide and would provide even less clarity and uniformity than under the Harrison Act regime that Congress desired to replace. As noted above, the courts of appeals have, until now, recognized that the "standard of medical practice generally recognized and accepted" for purposes of the CSA, *Moore*, 423 U.S. at 139, is a national one. If, however, the Court were to hold that the CSA implicitly incorporates the views of each of the 50 States regarding acceptable practice with respect to the dispensing of controlled substances, the prosecution of physicians would become much more difficult. In most instances, there would be no state statutory law governing the particular matter in question, and defendants would be free to assert their own view of accepted medical practice in that State. See *Rosenberg*, 515 F.2d at 198 n.14 (physician's attempted defense that prescription of the drugs at issue in limited quantities was permissible under state law); *Leal*, 75

F.3d at 226-227 (pharmacist's attempted defense that state law permitted pharmacist to fill prescription without inquiring into its appropriateness).

Ironically, the court of appeals' decision presumes that Congress intended to make federal requirements under the CSA dependent upon the 50 States' different views of medical practice at precisely the same time that the States were moving away from local practice standards in favor of national ones. By 1970, when Congress enacted the CSA, the States were in the process of abandoning the "locality rule" that doctors were to be judged according to the standard of care "in the same or similar locality." Jon R. Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DePaul L. Rev. 408, 409 (1968-1969); see *id.* at 410 (noting that the rule "is about to disappear almost completely"); Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 Wis. L. Rev. 1193, 1234 ("[s]ince the 1960s, conventional wisdom has characterized the locality rule as an obsolete doctrine"). Some of the chief reasons that the States abandoned the locality rule were that it required plaintiffs to produce local experts, who might be unwilling to testify against a colleague, and that it effectively immunized doctors who, however low their standards, were the only ones in the community. Waltz, *supra*, 18 DePaul L. Rev. at 420; Silver, *supra*, 1992 Wis. L. Rev. at 1227; *Robbins* v. *Footer*, 553 F.2d 123, 128, 130 (D.C. Cir. 1977) (rejecting locality rule in the District of Columbia for similar reasons and, on that basis, vacating and remanding district court's disqualification of an expert witness who was not adequately expert in local practices). Where, as in most instances, no state statute specifies the standard of practice at issue, federal prosecutors would have to contend with all the problems that led to the rejection of the locality rule in malpractice

actions. There is nothing in the CSA, however, that supports such a result.

II. THE COURT OF APPEALS' REJECTION OF THE ATTORNEY GENERAL'S INTERPRETIVE RULING WAS BASED ON A FUNDAMENTAL MISUNDERSTANDING OF APPLICABLE PRINCIPLES OF STATUTORY CONSTRUCTION

A. The Controlled Substances Act Does Not Intrude Upon The Core Sovereignty Of The States In A Way That Implicates The Clear Statement Rule Of *Gregory* v. *Ashcroft*

Rather than follow *Oakland Cannabis*, *Moore*, and *Mississippi Band*, the court of appeals concluded that under *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), state law must control the question whether a physician's conduct constitutes a legitimate medical practice under the CSA, absent a clear statement by Congress that federal law should govern the inquiry. Pet. App. 11a. The court of appeals' holding represents a drastic and unwarranted extension of *Gregory* that would, in effect, require that virtually any exercise of federal regulatory authority satisfy a judicially-imposed "clear statement" test. There is no basis in this Court's precedents for such a rule.

The court of appeals majority had to reach back to the *Lochner*-era for support for the proposition that "direct control of medical practice is beyond the power of the federal government." Pet. App. 10a (quoting *Linder* v. *United States*, 268 U.S. 5, 18 (1925)). From that flawed premise, the court of appeals reasoned that the Attorney General's interpretive ruling "invokes the outer limits of Congress's power by encroaching on state authority to regulate medical practice." *Id.* at 12a (citing *Linder*). In the court of appeals' view, for federal law to determine the content of the Controlled Substances Act's "legitimate medical purpose" requirement would intrude upon "an area of law traditionally

reserved for state authority," *id.* at 11a, and thereby "alter the usual constitutional balance between the States and the Federal Government," *ibid.* (quoting *Gregory*, 501 U.S. at 460 (additional internal quotation marks and citations omitted)). Thus, the court concluded that, under *Gregory*, the Attorney General lacked authority to adopt the interpretive rule because the CSA did not make "unmistakably clear" that federal, rather than state, law would govern the legitimate medical purpose inquiry for purposes of federal law, *ibid.*

The court of appeals' conclusion that federal regulation of the distribution of controlled substances "alter[s] the usual constitutional balance between the States and the Federal Government" in a manner that implicate's *Gregory*'s "unmistakably clear" statement rule, Pet. App. 11a, fundamentally misunderstands that rule. *Gregory* concerned the question whether a provision in the Missouri constitution requiring state judges to retire at age 70 violated federal age-discrimination laws. 501 U.S. at 455. This Court noted that the Missouri constitutional provision at issue involved "the authority of the people of the States to determine the qualifications of their most important government officials," *id.* at 463—"an authority that lies at the heart of representative government," *ibid.* (internal quotation marks and citation omitted). *Gregory* stressed that a State's decision as to the tenure of and qualifications for its own judges was a "decision of the most fundamental sort for a sovereign entity." *Id.* at 460.

Gregory does not apply in a case in which an Act of Congress may have an effect on *private* conduct as to which a State may also have its own, potentially differing, views. By its terms, *Gregory* is limited to circumstances in which the application of federal law would encroach upon how "a State defines itself as a Sovereign." 501 U.S. at 460. And the courts of appeals, other than the Ninth Circuit in this case,

have recognized the need to restrict *Gregory* to such intrusions on a State's sovereignty. See *United States* v. *Lot 5, Fox Grove*, 23 F.3d 359, 362 (11th Cir. 1994) (noting that "the *Gregory* plain statement preemption rule is limited to federal laws impacting a state's self-identification as a sovereignty"); *Gately* v. *Massachusetts*, 2 F.3d 1221, 1230 (1st Cir. 1993) (noting that *Gregory* is limited to protecting "a core function going to the 'heart of representative government'").

Contrary to the view of the majority below, *Gregory*'s clear statement rule does not apply whenever the federal government "exercise[s] control over an area of law traditionally reserved for state authority." Pet. App. 11a. Rather, *Gregory* emphasized that the State's interest in setting the qualifications of judicial office went "*beyond* an area traditionally regulated by the States," to the core of state sovereignty. 501 U.S. at 460 (emphasis added). See *City of Edmonds* v. *Oxford House, Inc.*, 514 U.S. 725, 732 n.5 (1995) (emphasizing the same with respect to *Gregory*). The court of appeals' expansion of *Gregory* would mean that virtually every federal regulation would need a clear statement from Congress, since the States' regulatory powers encompass everything not forbidden by the Constitution. *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 311 (1981) ("[T]he reserved police powers of the States * * * are plenary unless challenged as violating some specific provision of the Constitution.").

The court of appeals' view that federal regulation of the distribution of controlled substances raises significant constitutional concerns is incorrect both as a matter of history and this Court's precedents. The application of the CSA at issue here does not encroach on "an area of law traditionally reserved for state authority," Pet. App. 11a, because, as *Glucksberg* makes clear, there *is* no tradition of State's authorizing physician-assisted suicide. 521 U.S. at 723. Similarly, with respect to controlled substances more gener-

ally, Congress has regulated prescriptions for 90 years under the CSA and its predecessor, the Harrison Act, and that regulation has always involved federal evaluation of the medical uses of controlled substances. *Moore*, 423 U.S. at 142; *Webb*, 249 U.S. at 99-100; see pp. 24-36, *supra*.

The court of appeals cited *Linder* as authority for the proposition that "direct control of medical practice in the states is beyond the power of the federal government," Pet. App. 10a, and for the further conclusion that the Attorney General's interpretive ruling "invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice," *id.* at 12a. Notably, the Court's *Lochner*-era decision in *Linder* relied upon the then-prevailing view, articulated in such cases as *Hammer* v. *Dagenhart*, 247 U.S. 251 (1918), that certain categories of conduct were beyond Congress's enumerated powers, such as its power under the Commerce Clause. *Linder*, 268 U.S. at 17 (citing *Hammer*, among other decisions, for the proposition that "an act of Congress ostensibly enacted under power granted by the Constitution, not naturally and reasonably adapted to the effective exercise of such power but solely to the achievement of something plainly within power reserved to the States, is invalid and cannot be enforced"). That holding of *Hammer* was expressly overruled in *United States* v. *Darby*, 312 U.S. 100, 115-117 (1941). The Ninth Circuit's approach threatens to resurrect the long-discredited categorical approach of *Hammer* for purposes of a clear statement test. Such an approach would prove no more workable as a matter of clear statement jurisprudence than it did as an interpretation of the Commerce Clause.

In any event, this Court's decisions applying the CSA, and similar decisions dating back to the *Linder*/*Lochner* era, establish that the federal government *can* regulate the distribution of controlled substances. *Minor* v. *United States*, 396 U.S. 87, 98 n.13 (1969) (ban on sale of narcotics is within

Congress's constitutional power); *Reina* v. *United States*, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws"). Further, the Court has made clear that *Linder* provides no defense against the prosecution of a physician under a statute enacted pursuant to Congress's constitutional powers. In *Lambert* v. *Yellowley*, 272 U.S. 581 (1926), the Court rejected a physician's argument that he was immune from prosecution under federal prohibition laws because he was distributing liquor as a "medicinal agent" and because, in the words of *Linder*, "control [over] medical practice in the states is beyond the power of the federal government." *Id.* at 596. The Court made clear that "[t]here is no right to practice medicine which is not subordinate to * * * the power of Congress to make laws necessary and proper" to its constitutional authority. *Ibid.*[16]

Subsequent decisions of the Court have further established that the CSA is binding federal law even when it renders unlawful practices deemed permissible under state law. See *Oakland Cannabis*, 532 U.S. 492-493 (upholding federal determination in the CSA that marijuana lacks an acceptable medical use, despite state law purporting to recognize such medical uses); *Moore*, 423 U.S. at 139, 141-142, 143 (recog-

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[16] In addition to *Gregory*, the court of appeals also cited *Solid Waste Agency* v. *United States Army Corps of Engineers*, 531 U.S. 159 (2001), as establishing a clear statement rule where a regulation "invokes the outer limits of Congress' power." Pet. App. 12a (quoting *Solid Waste Agency*, 531 U.S. at 172). In *Solid Waste Agency*, the Court applied the doctrine of constitutional avoidance: "Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result." 531 U.S. at 172. The "significant constitutional question[]" avoided in *Solid Waste Agency* was whether application of the Clean Water Act to "nonnavigable, isolated, intrastate waters" would be within Congress's Commerce Clause authority. *Id.* at 172-173. There is no similar constitutionally dubious application to be avoided here. As the Court held in *Minor* and *Reina*, regulation of the distribution of controlled substances pursuant to the CSA does not "invoke[] the outer limits of Congress' power" or "push the limit of congressional authority" under the Commerce Clause. *Ibid.*

nizing that "provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits," and upholding CSA conviction based upon a finding that the physician's "experiment[al] * * * theory of detoxification" was not "in accordance with a standard of medical practice generally recognized and accepted in the United States"). See also *Rosenberg*, 515 F.2d at 198 n.14 (rejecting physician's defense against CSA prosecution that prescriptions were not impermissible under state law, explaining that "[t]he question of whether federal criminal laws have been violated is a federal issue to be determined in federal courts"); *Leal*, 75 F.3d at 227 (rejecting a pharmacist's defense that state law imposed no duty to identify suspicious prescriptions because "[w]hether state law imposes an equivalent civil or criminal duty is irrelevant" to whether the pharmacist violated his "federal duty" under the CSA).

Beyond the area of controlled substances, Congress has extended federal regulatory authority over other subject matters that also may have an impact on the practice of medicine. The federal government has regulated the composition and labeling of drugs since 1906, and medical devices since 1938, see *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475-476 (1976), and does so in a manner that turns on federal determinations regarding the safety and effectiveness of those medical products or devices. See, *e.g.*, 21 U.S.C. 355(d) (requiring FDA to deny application for new drug that has not been determined to be safe and effective for its intended purpose); 21 U.S.C. 352(j) (2000 & Supp. II 2002) (drug is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"). The federal Medicare program also establishes federal standards for "medically necessary" treatment. 42 U.S.C. 1320c-5(a)(1) and (b) (requiring any "health care practitioner" participating in Medicare to provide only "medically

necessary" services to Medicare beneficiaries, and allowing the Secretary to bar violators from participating in the Medicare program); 42 U.S.C. 1395y(a)(1)(A) (2000 & Supp. I 2001) (authorizing Medicare to reimburse only "reasonable and necessary" medical services).

In short, Congress often attaches consequences under federal statutes to a determination by a federal official regarding what constitutes proper, necessary, safe, or effective medical care. See *Medtronic*, 518 U.S. at 475 ("Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people."). The uniform application of such statutory schemes is cast into doubt by the court of appeals' decision in this case.

B. The Presumption Against Preemption Of State Law Furnishes No Basis For Refusing To Give Uniform Effect To A Provision Of Federal Law

In addition to the clear-statement rule of *Gregory*, the court of appeals also invoked a presumption against federal preemption of state law as a reason to invalidate the Attorney General's interpretive ruling. See Pet. App. 14a-15a (citing *California Div. of Labor Standards Enforcement* v. *Dillingham Constr. N.A., Inc.*, 519 U.S. 316, 325 (1997)). That presumption is inapposite here because the question is whether the Attorney General's interpretive ruling about the meaning of a prescription *for purposes of federal law* is valid, not whether it preempts Oregon's assisted suicide law. When a "state statute is pre-empted by federal law," it is thereby rendered "invalid under the Supremacy Clause of the Constitution." *California Fed. Sav. & Loan Ass'n* v. *Guerra*, 479 U.S. 272, 280 (1987). There is simply no issue of preemption or the Supremacy Clause in this case. At most, there is a concern that the federal law frustrates the purposes of Oregon's voter initiative. As Oregon has conceded,

the Attorney General's interpretive ruling "does not suggest that the [Oregon law] is invalid. He asserts only that his authority over controlled substances allows him to prevent * * * use [of such controlled substances] for purposes authorized by the Oregon law." Or. Br. in Opp. 9 n.7. Oregon's law remains valid and continues to have the effect of "exempt[ing] physicians who comply with the provisions of the * * * from prosecution under [Or. Rev. Stat. § 161.125(b)(1) (2003)]," which otherwise makes it a crime under state law for anyone, including a physician, to aid a suicide. *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994). Moreover, to the extent doctors in Oregon dispense substances other than those regulated under the CSA to hasten their patients' deaths, the Attorney General's interpretive ruling has no relevance to their conduct.

Oregon's de-criminalization law for physician-assisted suicide is no more preempted than California's laws de-criminalizing the possession and use of marijuana for medical purposes was preempted in *Oakland Cannabis*. Both state statutes have undeniable effects on state law. But despite their ability to remove parallel and duplicative state-law prohibitions, States are not free to displace the federal-law duty to comply with the CSA. See *Oakland Cannabis*, 532 U.S. at 494-495 (CSA precludes "medical necessity" defense, despite a California law recognizing marijuana's purported medical utility). The continued existence of the federal-law prohibition may frustrate the achievement of the full purposes of the change in state law, but that has never been enough to raise a concern about preemption. Such a view would stand the Supremacy Clause on its head, presumptively "preempting" federal law whenever it frustrated the purposes of state law.[17]

[17] The Ninth Circuit's *Linder* analysis can be understood as a kind of reverse field preemption, at least for clear statement purposes, and its presumption against preemption analysis can be understood as a kind of reverse conflict preemption analysis. Both stand the relevant Supremacy Clause analysis on its head.

C. The Additional Reasons Given By The Court Of Appeals For Invalidating The Attorney General's Interpretive Ruling Are Also Flawed

1. The court of appeals suggested that the Attorney General's interpretation was not entitled to deference because Congress intended to limit the CSA "to the field of drug abuse and addiction." Pet. App. 23a; accord *id.* at 13a-14a & n.7, 17a, 24a. As an initial matter, the taking of drugs to commit suicide *is* a form of "drug abuse." Congress intended that controlled substances be used for "medical" purposes, a word that connotes cure, amelioration, treatment, or prevention of disease. See pp. 18-19, *supra*. Indeed, a necessary condition under the CSA for a controlled substance to be dispensed by a physician is that it have a "currently accepted *medical* use in *treatment* in the United States." 21 U.S.C. 812(b) (emphasis added). And the term "drug" is itself defined in federal law as an article intended for "diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. 321(g)(1)(B); see 21 U.S.C. 802(12) (incorporating definition of Section 321(g)(1)). Thus, by definition, intentional use of a drug to take a life, rather than for one of the purposes identified in the statute, is a form of drug "abuse."

Moreover, in enacting the CSA, Congress expressly stated its goals broadly as encompassing "illegal importation, manufacture, distribution, and possession and *improper use* of controlled substances." 21 U.S.C. 801(2) (emphasis added). A Congress concerned with fatal overdoses, House Report 34, could hardly be unconcerned with intentional overdoses. Indeed, there is no doubt that Congress viewed the use of controlled substances for suicide to be a form of abuse or improper use. The House Report specifically referred to the "[m]isuse of a drug in suicides and attempted suicides," and noted that "injuries resulting from unsupervised use are re-

garded as indicative of a drug's potential for abuse." *Id.* at 35; see *id.* at 34 (potential for abuse indicated by "evidence that individuals are taking the drug * * * in amounts sufficient to create a hazard to their health") (internal quotation marks and citation omitted); 21 U.S.C. 801(1) (noting congressional purpose "to maintain the health and general welfare of the American people"); 21 U.S.C. 823(f)(5) (requiring the Attorney General to consider threats to "the public health and safety" in issuing and revoking registrations of physicians to distribute controlled substances).

2. The court of appeals also stated that the Attorney General's interpretive rule was beyond his authority because it intruded upon the role of the Secretary of Health and Human Services under the CSA. See Pet. App. 15a, 17a-19a & n.10. The CSA does expressly assign certain functions with respect to its implementation to the Secretary, but the Attorney General shares a role even in many of those functions. *E.g.*, 21 U.S.C. 811 (allocating to both the Attorney General and the Secretary responsibility for assessing factors in subsection (c) for scheduling a substance); 21 U.S.C. 823(f) (assigning to both the Secretary and the Attorney General roles in assessing proposed research projects relating to schedule I drugs). However, many other responsibilities under the CSA that require making determinations respecting the "legitimate medical use" of substances are assigned to the Attorney General alone. For example, under 21 U.S.C. 823(a)(1), the Attorney General is responsible for ensuring an adequate supply of schedule II substances for "legitimate medical * * * purposes," which obviously requires that he first determine what are such legitimate purposes. Similarly, only the Attorney General can determine whether a physician has violated federal drug laws or engaged in activities that threaten the public health and safety for the purpose of making registration decisions under the Act. See 21 U.S.C. 823(f), 824(a)(4). Thus, the court of appeals' categorical statement that only the Secretary may "make medical decisions under the Act," Pet. App. 18a, is incorrect. In any event, the determination whether dispensing drugs to facilitate suicide constitutes a "legitimate medical use" in "treatment" is a legal issue that turns on an interpretation of the CSA and a regulation of the Attorney General, and does not require an assessment of technical medical or scientific evidence of the sort that the CSA has assigned to the Secretary in other contexts.

The court of appeals cited (Pet. App. 15a) this Court's reference in *Moore* to the Secretary's function in determining "the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction." 423 U.S. at 144 (quoting 42 U.S.C. 257a (1970) (recodified at 42 U.S.C. 290bb-2a (2000)). That provision is not at issue here. Moreover, the fact that that provision expressly confers certain medical-related responsibilities on the Secretary reinforces the conclusion that the Attorney General is solely responsible for administering and interpreting provisions of the CSA and its implementing regulations where, as here, the relevant provisions do not give the Secretary any comparable role.[18]

The court of appeals also cited legislative history that it believed supported the conclusion that the Secretary is the

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[18] Even if the Secretary were the appropriate decision-maker with respect to whether physician-assisted suicide is a "legitimate medical purpose" in the usual course of professional "treatment," that conclusion would not support the court of appeals' judgment. The OLC memorandum on which the Attorney General based his interpretive ruling explained that the Secretary, through the Centers for Medicare and Medicaid Services, had already determined that physician-assisted suicide is "not reasonable and necessary to the diagnosis and treatment of disease or injury." Pet. App. 120a-121a (quoting the policy that physician-assisted suicide is not eligible for reimbursement under Medicare); *Medicare Benefit Policy Manual* ch. 16, § 20 (2003). Thus, there is no conflict between the Attorney General's interpretive ruling and the views of the "principal health agency of the federal government." Pet. App. 18a.

appropriate decision-maker for medical issues under the CSA. Pet. App. 18a-19a. That reliance was misplaced. In the first place, the statements referred to by the court actually *confirm* the government's position here that medical standards under the CSA are uniform *federal* standards. They thereby undermine the court of appeals' principal rationale in this case—that those standards are governed by state law. For example, the House Report on the CSA stressed, with respect to "having federal officials determine the appropriate method of the practice of medicine," that "this section will provide guidelines, determined by the principal health agency of the *federal government*." Pet. App. 18a (quoting House Report 15) (emphasis added). Likewise, as the court of appeals noted, the House Report on the 1974 amendments to the CSA stated that "[a]ll decisions of a medical nature are to be made by the Secretary [of Health and Human Services]." *Id.* 19a (quoting H.R. Rep. No. 884, 93d Cong., 2d Sess. 6 (1974) (court of appeals' emphasis omitted)). Those passages leave no doubt that Congress understood the CSA to establish *federal* policy with respect to the medical decisions relevant to the statute's implementation.

Further, the legislative history cited by the court of appeals concerns the statutory provisions that expressly assign to the Secretary the responsibility for establishing methods of professional practice in the medical treatment of narcotic addiction. See p. 47, *supra*. Like the statutory provisions it describes, that legislative history further demonstrates that when Congress desired to made the Secretary the official responsible to set federal standards under the CSA, it did so expressly. The necessary implication is that, with respect to those responsibilities under the CSA that Congress assigned to the Attorney General, without reference to the Secretary, it is the Attorney General who interprets the Act and establishes the uniform federal standards for implementing the Act.

Finally, it is clear that the proper allocation of authority among federal actors was not the basis of the court of appeals' decision. If it had been, the proper resolution would have been to remand the question to the Attorney General to solicit the views of the Secretary. Instead, the court of appeals continued the district court's permanent injunction of the Attorney General's interpretive ruling. In fact, in a footnote, the court of appeals recognized that it's holding also precludes the Secretary from making a determination whether physician-assisted suicide is a "legitimate medical practice" under the CSA. Pet. App. 17a n.10. Thus, the lower court's discussion of the CSA's allocation of authority between the Attorney General and the Secretary is ultimately irrelevant to its decision.

3. The court of appeals' conclusion that the Attorney General violated 21 U.S.C. 823(f) by failing to consider all of the factors addressed in that section is also flawed. By its terms, Section 823(f) applies only to actions by the Attorney General to deny or revoke a CSA registration. The Attorney General's ruling at issue here is not such a denial or revocation. It is, rather, an interpretation of the *substantive* provisions of the Act, violation of which may in turn lead to a revocation of registration. In any event, Section 823(f) requires the Attorney General to consider a number of factors, including both compliance with state laws, 21 U.S.C. 823(f)(4), and others, such as "[c]ompliance with applicable * * * Federal * * * laws" applicable to controlled substances, 21 U.S.C. 823(f)(4), and any threat to the public health and safety, 21 U.S.C. 823(f)(5), that plainly call for an independent determination by the Attorney General. The court of appeals' ruling would preclude the Attorney General from exercising his statutory responsibility to ascertain whether a physician's registration is consistent with the public interest by requiring the Attorney General to make one factor—compliance with state law—determinative of

that question, and indeed determinative of the question whether dispensing drugs to facilitate suicide even violates the CSA in the first place. There is no support in the CSA's text and purposes for those extraordinary conclusions.[19]

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be reversed, and the case remanded with instructions to dissolve any injunctions and dismiss.

Respectfully submitted.

PAUL D. CLEMENT
Acting Solicitor General
PETER D. KEISLER
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
GREGORY G. KATSAS
Deputy Assistant Attorney General
DOUGLAS HALLWARD-DRIEMEIER
Assistant To The Solicitor General
MARK B. STERN
JONATHAN H. LEVY
Attorneys

MAY 2005

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[19] The court of appeals also stated, without explanation, that the Attorney General's construction of 21 C.F.R. 1306.04 was not entitled to deference because it conflicted with this Court's interpretation of that provision in *Moore*. See Pet. App. 22a. That characterization of *Moore* is difficult to comprehend. *Moore*'s only substantive discussion of Section 1306.04 (then Section 306.04) notes with approval that the regulation "makes * * * explicit" the "medical purpose requirement" implicit in 21 U.S.C. 829's requirement of a "prescription." 423 U.S. at 136-137 nn.12 & 13. That conclusion is fully consistent with the Attorney General's interpretation of his regulation at issue here. The discussion on the particular page of the *Moore* opinion referred to by the court of appeals, Pet. App. 22a (citing 423 U.S. at 144), confirms that "physicians who go beyond approved practice remain subject to serious criminal penalties." That too is entirely consistent with the Attorney General's position here.

No. 04-623

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In The

Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR AMICUS PHYSICIANS FOR COMPASSIONATE CARE EDUCATIONAL FOUNDATION IN SUPPORT OF PETITIONERS

GREGORY P. LYNCH
Counsel for Physicians for Compassionate Care Educational Foundation
747 SW Mill View Way
Bend, OR 97702
(541) 408-0122
Attorneys for Amicus Curiae

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801, et seq., and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iii
INTEREST OF AMICUS CURIAE	1
ARGUMENT	1
CONCLUSION	11

TABLE OF AUTHORITIES

Page

CASES

Washington v. Glucksberg, 521 U.S. 702 (1997) 3, 8

STATUTES

ORS 127.800 2

ORS 127.885 ..... 2, 3

ORS 127.800 to 127.897 3

OTHER AUTHORITIES

Oregon Medical Association, Articles of Incorporation and Bylaws Oregon Medical Association, amended November 8, 2004, Chapter XII, 12.030 http://www.theoma.org/Files/BYLAWS%284%29.doc#Chapter_XIIt 3

21 CFR Appendix D 4

Appendix A, pp. A1-A27 4

Seventh Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2005 ..... 4, 10

H.R. Re. No. 1444, 91st Cong. 2d Sess. Pt. 1., at 35 (1970) 6

Appendix A, p. A16 7

Fromme, E.K., Tilden, V.P., Drach, L.L., and Tolle, S.W., *Increased Family Reports of Pain or Distress in Dying Oregonians: 1996 to 2002*, Journal of Palliative Medicine 2004; 7(3):431-442 8

TABLE OF AUTHORITIES – Continued

Page

Chevlen, E.M. and Smith, W.J.: *Power over Pain,* Stubenville, Ohio: International Task Force (2002) 8

Department of Health and Human Services: National Strategy for Suicide Prevention, 2001, http:/www.mentalhealth.samhsa.gove/publications/allpubs/SMA01-3417/ 9

Ganzini, L., and Farrenkopf, T. *Mental Health Consultation and Referral,* The Oregon Death with Dignity Act: A Guidebook for Health Care Providers. Edited by Haley, K. and Lee, M. Portland, Oregon: Oregon Health Sciences University (1988) 10

INTEREST OF AMICUS CURIAE

Physicians for Compassionate Care Educational Foundation is an association of physicians and other health professionals dedicated to preserving the traditional relation of the physician and patient as one in which the physician's primary task is to heal the patient and to minimize pain.

The association promotes the health and well being of patients by encouraging physicians to comfort patients and to assist those who are dying by support systems, minimizing pain, and treating depression. The association affirms the health restoring role of the physician and works to educate the profession and the public to the dangers of euthanasia and physician-assisted suicide. As physicians, we come from primary care specialties as well as subspecialties. We work to support each other and to speak out for the inherent value of human life.[1]

ARGUMENT

The Attorney General's interpretation of the Comprehensive Federal Statute must prevail over State law that departs radically from the traditionally accepted legal and ethical norms of medical practice in this country.

[1] Physicians for Compassionate Care files this brief with the consent of all parties. The Letters granting consent of the parties are attached hereto with the filing of this brief. Counsel for a party did not author this brief in whole or in part. No person or entity, other than Amicus Curiae, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

The Attorney General clearly acted reasonably and appropriately in concluding that the dispensing of drugs to assist a person in committing suicide is not a "legitimate medical purpose", nor is it "treatment" within the meaning of the Controlled Substances Act, a conclusion maintained by 49 States, the federal government, and leading associations of the medical profession.

Oregon's Death with Dignity Act (Or. Rev. Stat. 127.800 *et seq.* (2003)) (the Act) does not allow for doctor-assisted suicide within the context of a "legitimate medical purpose." The Act functions by singling out a particular class of individuals and excluding them from the normal protections generally afforded medical patients. In particular, the Act exempts Oregon doctors who write deliberately lethal prescriptions from meeting the accepted standard of care, and otherwise conforming their practice to the ethical standards of the medical profession. Oregon's Death with Dignity Act is a radical departure from the long-accepted legal and ethical norms of the medical profession and puts a defined group of patients and their families beyond the protections afforded by these protocols.

Specifically, the Act disallows recourse to malpractice suits by these patients and their family members in that it exempts assisted-suicide doctors from the requirement of meeting the ordinary standards of medical care in like communities nationally, and instead holds them only to a "good faith" standard, which is something heretofore unknown in a medical-legal sense, and inapplicable to any legitimate medical treatment. ORS 127.885 §4.01(1) states, "No person shall be subject to civil or criminal liability or professional disciplinary action for participating in good faith compliance with ORS 127.800 to

127.897." The statute actually replaces traditional "standard of care" requirements with a "good faith" standard that is, in essence, totally subjective, and virtually impossible to evaluate within the established context of medical practice, and treats assisted-suicide as different from any legitimate medical purpose or treatment.

Furthermore, the Act protects physicians who facilitate suicide against any professional discipline, provided only that the physician act in "good faith". Specifically, the Act provides, "No professional organization or association, or health care provider, may subject a person to censure, discipline, suspension, loss of license, loss of privileges, loss of membership or other penalty for participating or refusing to participate in good faith compliance with ORS 127.800 to 127.897." ORS 127.885 §4.01(1). At the same time, the American Medical Association, the American Nurses Association, and the American Psychiatric Association have all stated in a joint brief in *Washington v. Glucksberg,* 521 U.S. 702 (1997) that physician-assisted suicide is "fundamentally incompatible with the physician's role as healer". This statement is derived from the published ethics of the American Medical Association, Handbook of Medical Ethics, and emphasizes that assisted-suicide, as determined by the medical profession, not only falls outside the bounds of ethical medical practice, it is actually incompatible with medical practice.

Adherence to the ethical standards of the American Medical Association is also required by and for membership in the Oregon Medical Association (Articles of Incorporation and Bylaws Oregon Medical Association, amended November 8, 2004, Chapter XII, 12.030, http://www.theoma.org/Files/BYLAWS%284%29.doc#Chapter_XIIt). Oregon is the only state that has so radically departed from accepted

standards so as to allow for assisted-suicide, by removing this specific procedure from the ethical requirements of the prevailing medical organizations, and which otherwise apply to all other legitimate medical treatments within its borders. These facts further demonstrate the reasonableness of the Attorney General's conclusion based on the Office of Legal Counsel memorandum, dated June 27, 2001, that assisted suicide cannot be considered a "legitimate medical purpose" or "treatment."[2]

The case of Michael P. Freeland[3] poignantly demonstrates how Oregon's radical deviation from the long-accepted legal and ethical norms has resulted in the abuse of federally controlled substances to the detriment of innocent and vulnerable patients. This case is the only case involving a patient who was prescribed assisted-suicide drugs in Oregon that is based on an actual outside examination of medical records, court documents, and patient and family interviews. The official Oregon reports, which have been so roundly criticized as more protective of the Oregon Death with Dignity Act than of the vulnerable patients derives almost all of its information from the assisted-suicide doctors themselves.[4]

Mr. Freeland, an Oregon resident, developed lung cancer in his early sixties. Suicidal feelings had haunted him since he was twenty-one after his mother had died from a self-inflicted gunshot wound. Freeland actually

[2] 21 CFR Appendix D.

[3] Appendix A, pp. A1-A27.

[4] Seventh Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2005, p. 4.

attempted suicide shortly after his mother's death and was treated for depression in a psychiatric hospital. Still preoccupied with suicide, he made at least two additional suicide attempts. On each occasion, his suicidal despair was treated according to the generally accepted standards of medical care: he was deprived access to lethal means; he was protected until his suicidal impulses abated; and he was treated for depression and any other factors contributing to his despair.

With the treatment, Mr. Freeland did reasonably well until, when in his sixties, he was officially categorized as "terminally ill" in Oregon. Not surprisingly, his physician and a consultant chosen by that doctor opined that Freeland had a "terminal cancer", as defined by the Act, because, in their opinion, Freeland may not have more than six months to live. The Oregon Death with Dignity Act defines "terminal disease" as an "incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death *within six months* (emphasis added). ORS 127.800 s.1.01(12). The fact that this prognosis underestimated Michael Freeland's actual longevity by nearly two years served no protective function for this unfortunate man. He was, under the Act, technically eligible for formal medical assistance in killing himself, in lieu of, and instead of being given the protection and medical treatment he had successfully received on prior occasions.

The physician, well known for his political activity promoting legalized assisted suicide, prescribed this distressed man a lethal overdose of federally controlled substances without so much as a cursory psychiatric examination. He did this despite the fact that the primary care doctor had diagnosed Freeland as depressed and had

given him an antidepressant medication for treatment, and despite the fact that Freeland's daughter had actually asked the assisted-suicide doctor if such an examination might not be in order.

By January 23, 2002, Mr. Freeland had become so depressed and confused that a doctor hospitalized him against his will because of suicidal and possibly homicidal ideation. While efforts were made to remove his guns from his home before his discharge from the hospital, the lethal prescription was left available to him. The prescribing physician actually admitted that he had made no attempt to retrieve these lethal drugs, which were federally controlled substances, even after the Multnomah County Circuit Court determined on February 12, 2002, that Freeland was incompetent to make his own medical decisions and had appointed Freeland a temporary guardian. Under traditional notions of "legitimate medical treatment," leaving this depressed, suicidal, confused, and legally incompetent individual unsupervised, and with access to a lethal dosage of a federally controlled substance would have been considered medically negligent and unethical. Congress referred to the "[m]isuse of a drug in suicides and attempted suicides" and "injuries resulting from unsupervised use" as evidence of improper use and of drug abuse under the CSA[5] and pointed to individuals taking controlled substances in "amounts sufficient to create a hazard to their health" as further evidence of misuse of a controlled substance and of "drug abuse."[6] However, under the Act, Oregon does not regulate assisted

[5] H.R. Rep. No. 1444, 91st Cong. 2d Sess. Pt. 1., at 35 (1970).

[6] See id. at 34.

suicide in the same way that it regulates medical treatments, presumably because assisted suicide cannot be, under traditional definitions, considered a medical treatment, even in Oregon.

While pain control initially did not present a problem for Mr. Freeland, it did in the final weeks of his life. During a home visit on November 17, 2002, volunteers from Physicians for Compassionate Care Educational Foundation found that he was taking very little or no pain medication. He said that he was desperate because of the pain and was on the verge of killing himself with a prescription that had been previously provided, and disclosed that the prescribing physician had actually offered to sit with him while he took the lethal drugs.[7] Instead, these volunteers insisted that this vulnerable and confused man be provided with the accepted standard medical care, and at the same time encouraged Mr. Freeland to take his pain medications. It was actually the volunteers who insisted that Mr. Freeland be provided with an intravenous infusion pump to administer adequate doses of opioid medications in order to control pain, and despite the fact that earlier a hospital palliative care consultant had found the need for attendant care to be a "moot point" since Mr. Freeland had available to him "life-ending medications." The consultant's comments, and the prescribing physician's deliberate failure to arrange for competent attendant care, quite clearly suggests that the availability of federally controlled substances for the purpose of facilitating Mr. Freeland's suicide actually interfered with his receiving adequate pain care, which care would otherwise

[7] Appendix A, p. A16.

have been given as consistent with the generally accepted medical standard of care and practice. Moreover, there is reason to believe that such attitudes have, in fact, contributed to the reported decrease in the adequacy of pain care among Oregon terminally ill patients since the implementation of Oregon's Death with Dignity Act.[8] Simply stated, there was absolutely no excuse for allowing this man to suffer with untreated pain after providing him with the means of killing himself by prescribing a lethal dose of a federally controlled substance instead of pain care.

At a number of Physicians for Compassionate Care Educational Foundation palliative pain conferences, numerous experts have taught that no one needs to die in unrelieved suffering. Noted national pain care expert, Eric Chevlen, has, along with others, explained how a vast array of treatments, including long-acting opiods, every-day nonsteroidal anti-inflammatories, sophisticated spinal infusion pumps, surgical procedures, and even therapeutic radio nucleotides, along with a host of other treatments, can and will relieve the suffering of patients.[9] Clearly Justice O'Connor in her concurring opinion in *Glucksberg*, supra, recognized that "The parties and *amici* agree that . . . a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication from qualified physicians to alleviate that suffering, even to the point of causing unconsciousness and hastening death". *Washington v. Glucksberg,* 521

[8] Fromme, E.K., Tilden, V.P., Drach, L.L., and Tolle, S.W., *Increased Family Reports of Pain or Distress in Dying Oregonians: 1996 to 2002,* Journal of Palliative Medicine 2004; 7(3):431-442.

[9] Chevlen, E.M. and Smith, W.J.: *Power over Pain,* Steubenville, Ohio: International Task Force (2002).

U.S. 702, 736-737 (1997). In every state in this country, including Oregon, and without recourse to assisted suicide, patients can receive pain care sufficient to relieve their suffering, even in the rare instance such treatment may unintentionally hasten death. In Michael Freeland's case, adequate pain care that did not hasten death was readily available, and the failure to provide that care in a timely fashion was unconscionable.

Not only was the prescription of a lethal dose of a federally controlled substance to Mr. Freeland the likely cause of his failure to receive timely and adequate pain management, the failure to treat this man's depression and suicidal despair according to locally and nationally accepted standards of medical care arose explicitly from the nature of the Oregon Death with Dignity Act and its implementing guidelines. Clearly Michael Freeland did not receive the consistent treatment of his suicidal despair that all medical standards of care require. He was not protected against access to lethal means, a crucial element in the accepted standard of practice when dealing with suicidal intentions.[10] Instead, he was actually provided access to a lethal overdose which, outside of the Act, would have been seen as medical malpractice and unethical behavior in any state. Even in Oregon, such a practice would otherwise be considered a form of medical negligence and would have been reportable to the Board of Medical Examiners as unethical behavior, without the protections and exemptions provided for in Oregon's Death with Dignity Act. For good reason, less than 0.5% of

[10] Department of Health and Human Services: National Strategy for Suicide Prevention, 2001, http://www.mentalhealth.samhsa.gove/publications/allpubs/SMA01-3517/.

Oregon's 10,000 doctors were found to have engaged in such behavior, which is so incompatible with the physicians role as healer.[11]

Frightening, but not surprising, published guidelines for implementing the assisted-suicide law actually provide that, "If the mental health professional finds the patient competent, refusal of mental health treatment by the patient does not constitute a legal barrier to receiving a prescription for a lethal dose of medication"[12] In such a case, assisted suicide is offered not as a legitimate medical and psychiatric treatment of suicidal despair as required by the rest of the country, but instead as an alternative to treatment. In every state in this country, including Oregon, the leading associations of the medical profession deem assisted suicide outside the scope of legitimate medical practice. Even the Oregon Death with Dignity Act does not define assisted suicide as a legitimate medical practice. It simply exempts that practice from the rules and regulations that otherwise define and control the practice of medicine within its boundaries.

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[11] Seventh Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2005, p. 4.

[12] Ganzini, L. and Farrenkopf, T. *Mental Health Consultation and Referral*, The Oregon Death with Dignity Act: A Guidebook for Health Care Providers. Edited by Haley, K. and Lee, M. Portland, Oregon: Oregon Health Sciences University (1998) p. 31.

CONCLUSION

Clearly, the Attorney General acted reasonably in concluding that dispensing drugs to assist a person to commit suicide is not for a "legitimate medical purpose" or "treatment", within the meaning of the Controlled Substance Act.

Respectfully submitted,

HURLEY, LYNCH & RE, P.C.
GREGORY P. LYNCH OSB 75234
Of Attorneys for Amicus Curiae

APPENDIX A

COMPETING PARADIGMS OF RESPONDING TO ASSISTED-SUICIDE REQUESTS IN OREGON: CASE REPORT

(Revised May 3, 2004)

By

N. Gregory Hamilton, M.D.

and

Catherine Hamilton, M.A.

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Corresponding author:

N. Gregory Hamilton, M.D.
2250 N.W. Flanders, Suite 306
Portland, Oregon 97210
(503) 276-1293
nghamil@comcast.net

INTRODUCTION

Legalization of assisted suicide in Oregon ushered in a new approach to evaluating suicidal patients with serious medical illnesses. Two competing paradigms – the traditional clinical (1-3) and the assisted-suicide competency (4) models – now exist. No more dramatic illustration of the

inconsistencies in these differing approaches can be found than the case of Michael P. Freeland.

This sixty-three-year-old lung cancer patient was admitted to Providence Hospital in Portland, Oregon, after he developed depression and was thought to have both suicidal and homicidal ideation. Before discharge from the hospital the attending psychiatrist noted in the medical record, "The guns are now out of the house, which resolves the major safety issue." The same summary also stated that the patient still had in his possession a legally prescribed, lethal dose of barbiturates, which he "keeps safely at home." When he returned home, he retained this means of suicide. While removal of guns may have resolved at least one safety issue, it did nothing to address another important safety concern; a lethal prescription intended for the purpose of suicide remained in the home of this depressed patient. This inconsistency very likely did not arise from any oversight on the psychiatrist's part, but from the competing paradigms informing his decisions.

This paper compares the traditional clinical approach to evaluating and treating suicidal symptoms with the assisted-suicide competency model delineated in an assisted-suicide guidebook (4) used in Oregon, the only state where such a practice is legal. The case of Michael Freeland illustrates these competing paradigms. This is the first reported case of a patient legally prescribed assisted-suicide drugs for which medical records have been made available. The patient, Michael Freeland, out of a wish to help others, agreed to numerous prospective interviews and generously provided his written consent for release to the authors of all medical records from Providence Portland Medical Center. And he granted permission for publication of his case without disguise.

CLINICAL MODEL

"No group of suicidal patients has been more ignored than those who become suicidal in response to serious or terminal illness" (1, p558), concludes the "Suicide, Assisted Suicide, and Euthanasia" section of *The Harvard Medical School Guide to Suicide Assessment and Intervention*. Herbert Hendin, author of this chapter, [and our discussant in this Symposium] points out that these individuals are no different from other suicidal individuals. While physical illness may be a precipitating cause of despair, these patients usually suffer from a treatable depression, he reminds us. Patients considering assisted suicide are deeply ambivalent about their desire for death, just as are other suicidal patients. This conclusion is consistent with evidence that poor health is not an independent risk factor for death by suicide but is correlated with depression or other mental illness as a key intervening variable (3,5). A noted, large scale study [published in JAMA] demonstrates that seriously ill individuals expressing an interest in assisted suicide all suffered from symptoms of depression or irrational hopelessness (6). Kissane (7) [who gave us such a lucid discussion earlier this afternoon] termed this later factor demoralization syndrome and found that hopeless feelings and depression were major contributing factors in the Australian assisted-suicide deaths during his country's brief experiment with the practice.

The clinical approach to dealing with assisted-suicide requests, as with other suicidal symptoms, begins with assessment. After a more open-ended portion of the interview aimed at empathically understanding the patient, the doctor typically inquires about the onset and recurrence of psychiatric symptoms, previous similar episodes and treatments, recent stresses, social and economic difficulties,

and religious or spiritual concerns (3). Symptoms of depression and substance abuse are noted. In this population, the clinician must pay particular attention to medications that can cause or exacerbate psychiatric disturbance, cancers or other illnesses known to cause depression or anxiety, the adequacy of pain control, and whether or not the patient has been reassured about the effectiveness of aggressive pain management and other palliative care interventions.

Thoughtful clinicians consider it equally important to explore sources of hope, self-esteem, and strength. At some point, the clinician directly asks about the seriousness and urgency of suicidal intent and the availability of means, including access to firearms and potentially lethal medications. The doctor must also explore the patient's ambivalence about dying, which is virtually always present (1).

When it comes to treatment, the approach in this population emphasizes an effort to "understand and relieve the desperation that underlies the request for assisted suicide" (1, p 553). To do so the clinician must resist assuming the role of "gatekeeper," who would focus on issues of competence alone (1,7,8). Such patients often suffer from feelings of worthlessness, demoralization, or guilt and may be making a plea for reassurance (1,7). Depressed patients may indulge in rigid, black-and-white thinking and overlook possible solutions to problems. They often have complex fantasies about their doctors; for instance, they might see the doctor from whom they are requesting suicide as a savior with whom they will unite in death or as an executioner or in any number of other roles (1). Exploring such feelings and fantasies and whatever other concerns arise can be reassuring and validating

for the patient and can go a long way toward dispelling feelings of demoralization and worthlessness.

As our co-presenter, Brian Kelly, so clearly demonstrated in the chapter he wrote with Varghese, "Countertransference and Assisted Suicide," physicians typically must deal with their own feelings of helplessness in the face of death (1,2,7,9). Various authors (2,10-12) have discussed the process of containing the feelings of troubling patients requesting assisted suicide through empathic listening, accepting whatever feelings of helplessness or other feelings that may arise, reflecting upon those feelings, and offering back to the patient understanding and meaning in the form of a comment or gesture.

Underlying physical illness may contribute to depression and must be treated if possible. While depression and fear, not pain, are the most frequent motivating factors for assisted suicide requests (2,3,6,13), pain care often can be improved. Antidepressant, antianxiety, or psychostimulant medication can play a crucial role in alleviating underlying depression or fear leading to desperation. Most psychiatrists have heard a patient convincingly describe a seemingly hopeless circumstance only to find the patient's perception of the very same circumstances entirely changed after a successful course of antidepressant medication.

While many patients with suicidal symptoms can be treated as outpatients, sometimes psychiatric hospitalization is required to protect the patient while treatment is initiated. Hospitalization may also be needed in those requesting assisted suicide.

A thorough assessment of patients nearing the end of life is often organized around a palliative care model that explores physical, psychological, social, and spiritual (14) contributions to symptoms. Palliative care specialists routinely perform this evaluation, but most experts agree that when requests for assisted suicide arise a psychiatric consultation is required (14, p2901).

The traditional clinical approach described here assumes that suicidal symptoms in the seriously ill should be evaluated and treated as they are in all other patients (15) and that such evaluation and treatment can be extremely helpful, often lifesaving.

ASSISTED-SUICIDE COMPETENCY MODEL

In contrast to the traditional clinical approach just described, the guidebook for Oregon assisted suicide emphasizes that mental health consultation, when required at all, should be "a form of a competency evaluation, specifically focused on capacity" (4, p 30) to make a decision. Ganzini and Farrenkopf, who authored the mental health section state, "The evaluation should focus on assessing the patient's competency and factors that limit competency such as mental disorders, knowledge deficits, and coercion" (4, p 30). When it comes to diagnosing a psychiatric disorder, however, these authors insist that the presence of a mental disorder does not disqualify a patient from assisted suicide. While acknowledging that depression may affect a patient's judgment about assisted suicide they emphasize, "The presence of depression does not necessarily mean that the patient is incompetent" (p31). This opinion is at variance with the majority of forensic psychiatrists, who believe "that the presence of

major depressive disorder should result in an automatic finding of incompetence" (16, p595) to make decisions about assisted suicide. A more nuanced approach proposed by Kissane (17), which includes assessment of demoralization in determining competency for assisted suicide, is not in use among Oregon assisted-suicide practitioners.

In the assisted-suicide competency model, as used in Oregon, there is no obligation to treat depression or any other mental illness even when one is found. The guidebook concludes, "If the mental health professional finds the patient competent, refusal of mental health treatment by the patient does not constitute a legal barrier to receiving a prescription for a lethal dose of medication" (4, p31).

The guidebook mentions the importance of determining the presence or absence of coercion as a part of competence determination. As these guidelines are applied, however, coercion is narrowly defined. Such was the case in the widely discussed assisted suicide of Kate Cheney (18-20), an eighty-five-year old cancer patient with growing dementia, whose psychiatrist believed she was being pressured by her family; nevertheless, she was given assisted suicide in Oregon.

The Oregon law requires that the patient who makes an initial assisted-suicide request be judged to have less than six months to live. A second physician must confirm the prognosis. The assisted-suicide doctor typically chooses this consultant. There must be a second assisted-suicide request after a fifteen day waiting period, and one of the requests must be in writing. There is no requirement for a psychiatric evaluation. Only if the doctor intending to write the prescription for overdose or the consultant believes that the patient has seriously impaired judgment

due to a mental disorder is there any requirement for referral to a psychiatrist. In actual practice, few patient's requesting assisted suicide are ever referred for such an evaluation. The percentage sent for mental health consultation prior to assisted suicide in Oregon has steadily dropped over five years to only 5% (21).

REQUEST FOR ASSISTED SUICIDE BY A PSYCHIATRIC PATIENT

These two distinct paradigms for dealing with suicidal ideation in the seriously ill can become competing approaches as illustrated by the care of a single individual, Michael Freeland.

Just after receiving a cancer diagnosis, this 62-year-old man made a telephone call to Physicians for Compassionate Care (PCC), a medical group dedicated to improving the care of the seriously ill without ever resorting to or condoning assisted suicide or euthanasia. He seemed to be asking about how to get the process of assisted suicide started. Although he did not say so, he may have intended to call the Compassion in Dying Federation (CDF), a politically active group that shepherds over three quarters of assisted suicides in Oregon. Or, this well informed man may have known about PCC and called this organization as a cry for help. At any rate, the call was answered by a volunteer, my co-author, Cathy Hamilton, who was trained in counseling and helping the seriously ill and who is opposed to the practice of assisted suicide.

Mr. Freeland sounded distraught. He explained that he saw no purpose in undergoing chemotherapy. Although he had just received his prognosis, he was already making funeral arrangement, he said, and added, "I might as well

just end it." When Cathy empathized with how upset he must be, just having received such a dire prognosis, he became tearful. He said he did not want to tell his daughter about his cancer because she was moving to another state to attend graduate school and he did not want to interfere with her education. He lived alone.

Cathy explained her views on assisted suicide and assured him that with good palliative care his symptoms could be addressed. As she would have with any other suicidal individual, she told him she did not want him to kill himself and offered to help him find treatment for his depression. She promised to advocate for him and find a doctor who could treat any pain he might have or address other symptoms.

In subsequent conversations, he mentioned that he had felt haunted by suicidal feelings ever since his mother died from a self-inflicted gunshot wound when he was twenty-one. Shortly after her death, he attempted suicide himself and was treated for depression in a psychiatric hospital. He made at least two other suicide attempts and remained preoccupied with the possibility of suicide, he explained. Later, he developed alcoholism but joined alcoholics anonymous and remained sober for over twenty years. Despite intermittent depression, he was able to work as an electronics technician for a local television station. He was divorced and had a daughter and a few friends. For unknown reasons, he did not allow his daughter or friends into his home, and he kept elaborate surveillance cameras trained on the perimeter of his property.

Cathy kept frequent contact with Mr. Freeland during the next year. With encouragement, he did undergo

chemotherapy and radiation treatment for his cancer, which alleviated his symptoms significantly.

Near the anniversary of his receiving a terminal prognosis, however, he announced, "I have the pills." He received the prescription from Doctor Peter Reagan, an assisted-suicide advocate who was associated with CDF. Doctor Reagan had already described in *Lancet* (22) giving an overdose to another patient diagnosed with depression (2,23). He referred that woman for a competency evaluation (2,20,23), which cleared her for assisted suicide approximately two weeks after he met her. In contrast to that case, Reagan commented that he did not think a psychiatric consultation would be "necessary" for Mr. Freeland, according to his daughter who accompanied him to an appointment.

Mr. Freeland mentioned that another member of Compassion in Dying had been calling him regularly to talk with him about the assisted-suicide option. He had seen her on a television show, which he said "convinced me it [assisted suicide] was the way to go." When asked if that doctor knew about his depressions and suicide attempts, Freeland said, "She didn't get into that. Our conversations have been superficial."

With urging, the patient finally let his daughter know about his cancer. She gladly postponed her graduate studies and returned to care for him. Cathy urged him to take the 50 mg. of sertraline his primary care doctor prescribed for his depression. While he continued to be suspicious, kept a variety of loaded assault weapons in his home, and used his surveillance cameras as always, he did begin to allow a few people, including his daughter and Cathy, into the house for the first time. Cathy received

permission to communicate with his primary care doctor and initiated home visits in an effort to help him overcome his depression and his fears of the dying process.

Six months later, Mr. Freeland could not be reached for several days. The doctor's office mentioned that their patient had begun having more "mental problems" and had been admitted to the hospital psychiatry ward. After his ex-sister-in-law began pursuing guardianship, according to a psychiatric report, he grew upset. He had saved a substantial amount of money, and it was important to him to retain control of his resources. His doctor became worried that the patient was increasingly suicidal, or even homicidal, and he arranged for the patient to be placed on an involuntary hold.

The emergency room physician's report showed that she evaluated him for "possible suicidal or homicidal ideation." A psychiatric social worker and a mental health technician both described possible suicidal and homicidal ideation. The social worker report mentioned that threats may have been made toward a hospice nurse and toward his daughter. Both reports documented the history of a previous overdose, following his mother's suicide. When he was admitted to the hospital and evaluated by the inpatient psychiatrist, however, possible homicidal comments were featured prominently in the chief complaint and suicidal intentions were all subsumed under discussion of an interest in assisted suicide. The psychiatrist's report denied a history of suicide attempts, without any attempt to reconcile this comment with documentation from emergency room personnel that there was a history of suicide attempts. Other than these two omissions and the failure to account for the paranoia mentioned by the

emergency room doctor, the psychiatric record was fairly consistent with the known history.

The inpatient psychiatrist noted that the patient had diminished appetite and had lost 70 pounds, but his sleep was adequate with the numerous sedative medications he was taking. He reported confusion and some memory problems. In addition to sertraline, medications listed, without the dose, included diazepam, temazepam, hydromorphone, morphine oral solution, rofecoxib, salmeterol inhaler, pirbuterol inhaler, choline, and laxalose.

The mental status report described him as thin and tearful. His speech was clear. His affect was discouraged. His thought processes were well organized, and he denied thoughts of harming himself or others. Paranoia was not mentioned in the psychiatric examination. He was alert and oriented and judged to have above-average intelligence. Laboratory studies showed hemoglobin was mildly low (12.4 g/dL), but his blood count and chemistry screen were otherwise normal.

The psychiatrist diagnosed him with depression not otherwise specified as the primary diagnosis, chronic adjustment disorder with depressed mood, probable intermittent delirium, narcissistic personality traits, and metastatic lung cancer with guarded prognosis.

During the patient's inpatient stay, a social work home visit revealed that his home was uninhabitable – with heaps of clutter, rodent feces, ashes extending two feet from the fireplace into the living room, lack of food and heat, etc. Thirty-two firearms and thousands of rounds of ammunition were removed by the police. The lethal medications, however, were left. Although the

psychiatrist noted in the discharge summary that the patient would continue to be subject to intermittent delirium, he did not seem to consider the presence of a lethal overdose in the house potentially problematic. Concerning the need for attendant care, a palliative care consultation obtained by the psychiatrist said the fact that the patient had "life-ending medications" may make that problem "a moot point."

The day after discharge, the same psychiatrist wrote a letter to the court supporting guardianship by saying he "is susceptible to periods of confusion and impaired judgment." He concluded that Mr. Freeland was unable to handle his own finances and that his cognitive impairments were unlikely to improve.

At a subsequent home visit, Mr. Freeland reminded Cathy that he had already far outlived the original six months to live prognosis; and he added that the assisted-suicide doctors gave him a new six months to live prognosis so his assisted suicide would be "legal." That was at least ten months prior to his eventual death, which took place nearly two years after he was first given a prognosis of less than six months to live.

Cathy redoubled her efforts to stay in contact with him and encourage him. Fortunately, so did some old friends from AA and others, who began to visit him daily. His house was cleaned up and refurbished; and his mood brightened. Cathy encouraged him to relinquish his lethal barbiturate prescription, but he refused to do so.

Two months later he entered the hospital briefly to be treated for dyspnea. The medical record described him as tearful and as having labile affect. He was thought to have "steroid psychosis" and was tapered off of steroid

medication. This confused man was sent home, once again, with the lethal drugs in his possession.

Over the coming months, he received antidepressants, social and spiritual support, and encouragement. A friend spent most days with him. His few friends were clear that they valued him and did not want him to kill himself. Hospice, however, remained "neutral" on this issue, and he grew suspicious of that organization. As he put it, "I'm going to get rid of hospice. I don't trust them. Then there's the morphine. I'm not in any pain. I don't know why they want me to take all this morphine." He dismissed hospice, decreased the pain medication, and both his mood and cognitive clarity improved for several months.

Three weeks prior to his death, however, pain became a significant factor again. As his pain increased, he used more controlled-release oxycodone, which contributed to constipation, which in turn became excruciating in itself. Because of abdominal discomfort, he stopped drinking fluids, as well as eating, and became confused and more suspicious again. He now wondered what might be in the liquids people gave him and in the pain medications, so he didn't take them. At a home visit by Cathy and me, his medication tray showed that he was taking minimal, if any pain medication. He said that he was desperate because of the pain and was on the verge of killing himself with the overdose and that Doctor Reagan had recently offered to sit with him while he took it.

We explained that he was frightened because of his confusion, but that pain medication and fluids, along with 24-hour care, would help him. Fluids might also help alleviate his constipation, which had become so painful. We handed him the controlled-release oxycodone tablets

from his bedside stand, and he took them as prescribed for the first time in days. Cathy then insisted that his doctor should prescribe a morphine pump to be delivered the next day so his confusion would not interfere with his receiving needed pain relief. She also arranged for a 24-hour attendant care, which he could readily afford. With these interventions his confusion cleared, his pain abated, and he felt much relieved during the remaining two weeks of his life, even while his physical condition deteriorated.

During this time, which he had been on the verge of cutting short, he was able to express his gratitude to and say goodbye to the many people who had helped him. Most important, he was able to reconcile with his daughter, from whom he had been alientated since the psychiatric hospitalization. She enthusiastically renewed her relationship with him. This opportunity was very meaningful to her as well as to him.

DISCUSSION

Removing lethal means is central to the clinical treatment of suicidal symptoms; but providing lethal means is central to the assisted-suicide model. These and other differing approaches of the competing paradigms revealed themselves in different ways among the many individuals involved in Michael Freeland's care.

Cathy, who was a volunteer for Physicians for Compassionate Care, and members of Compassion in Dying Federation (CDF) took openly competing approaches. Cathy considered the patient's current depression central to his motivation to kill himself. She took his suicide threats seriously, especially in light of his having made previous attempts prior to developing a life threatening

illness. She recommended psychiatric evaluation and treatment; and, when he refused referral to such treatment, she spent long hours talking with him about his fears of death, his spiritual concerns, the trauma of his mother's suicide, his identification with his deceased parent, his depression and paranoid fears, and his past accomplishments and hopes for the future. She called the primary care doctor and encouraged him through communication with his nurse to provide antidepressant medication. She interacted with those who could visit with him. When he became desperate because of apparent delirium and poorly treated pain in the last few weeks, she made certain he received the pain care he needed and arranged for intensified palliative care, including 24-hour attendant care. She consistently reminded him that she did not want him to kill himself.

In contrast, according to the patient, neither CDF doctor seemed "very interested" in his psychiatric history and previous suicide attempts. Doctor Reagan, who prescribed the assisted-suicide drugs, told the patient and his daughter that even a psychiatric evaluation would not be "necessary." Perhaps the issue of whether or not Mr. Freeland was depressed or had made previous suicide attempts seemed irrelevant to CDF doctors, because, as the guidelines recommend, it is only competency to make decisions that is required legally. Doctor Reagan did offer to make a home visit and sit with the patient while he took the overdose, but he apparently was not aware of the patient's plight when he was delirious and desperate and not receiving enough pain medication. Neither did he seem aware that the inpatient psychiatrist did not consider Mr. Freeland competent to handle his own affairs and had

written a letter to that effect prior to the patient's six-months-to-live prognosis being renewed.

Other clinicians, however, took different approaches. The emergency room doctor, along with the social workers and court investigators at his psychiatric admission, considered his depression and previous suicide attempts most seriously. They discussed his physical illness as a complicating diagnosis. Even these notes, however, skirted the issue of his possessing a lethal overdose and focused more directly on homicidal than suicidal ideation, although the danger of suicide was clear. The health care professionals seemed placed in a clinical bind when presented with a suicidal mentally ill patient, who had been given an overdose by another doctor.

The inpatient psychiatrist seemed to mix both the traditional clinical approach and the assisted-suicide competency model with predictably mixed results. He did an evaluation, diagnosed the depression and intermittent delirium, and attempted to treat the depression. He protected the patient from danger to himself or others through inpatient treatment for over a week and recommended antidepressant medication and social support. He took care to make sure guns were removed from the home prior to discharging the patient. All of this is consistent with the traditional clinical model. In deference to the assisted-suicide competency model, however, he noted that the patient had been given a lethal prescription and left that prescription in his possession, despite having kept the patient hospitalized to protect him from harm to self or others. Perhaps his attempt to mix both approaches is what led him to list only homicidal danger in his notes without mentioning the history of suicide attempts or threats, except in the context of mentioning that he was

interested in assisted suicide and had received a lethal prescription.

It is even more perplexing to consider how the psychiatrist could leave the lethal drugs with his depressed patient, apparently believing he had a right to the overdose, and then could write a letter to the court only a day later, claiming the patient was not competent to make his own decisions. Perhaps he concluded he could not make decisions about finances but could make them about assisted suicide. Perhaps he felt it was within Doctor Reagan's purview to address that issue because he was the assisted-suicide doctor. He did not clarify his thinking about this issue in the medical record.

Not only did the mixing of models affect the psychiatric response, it also affected planning for adequate palliative care after discharge from the hospital. Following a detailed discussion of Mr. Freeland's medical history and condition, a hospital consultant asked to make recommendations for further medical and palliative care predicted that the patient most likely would be further incapacitated in a "matter of weeks" but that, because he has "life-ending medications," providing for additional care may be "a moot point." Those were the final words of the report and the consultant made no specific recommendations for further care. As a result, no attendant care was provided.

A most interesting clinical dilemma appears present for the primary care doctor. He initially used a mixed model but eventually switched to a clear, traditional clinical approach. He diagnosed depression early on and treated it with medication. While he did not provide assisted suicide himself, he willingly collaborated with the assisted-suicide doctors, thereby giving the patient a

mixed message. The patient said it was this primary care doctor who gave the six-months-to-live prognosis, which is needed to proceed with the assisted-suicide protocol – he did so twice. This approach is entirely consistent with the assisted-suicide competency model, which admits that depression can contribute to suicidal ideation but insists that the doctor can help him commit suicide anyway. When the patient became more desperate and confused, however, this doctor changed models and had him hospitalized against his wishes. This doctor's attempt to straddle both approaches, to create a kind of neutral zone, broke down in the end; and he was released from the case because of the patient's heightened distrust.

This case illustrates how difficult it is to combine the two paradigms of responding to suicidal ideation. Attempts to mix the clinical and the assisted-suicide competency models in this case resulted in perplexing clinical interventions, inconsistent approaches, and attempts to switch models during times of crisis.

We believe that the two approaches are incompatible, because they are based on differing underlying assumptions. The traditional clinical approach assumes that suicidal seriously ill individuals are no different from any other suicidal patient, and the wish for death is considered symptomatic of underlying psychiatric illness to be evaluated and treated. This treatment usually should be provided voluntarily, but when the danger is great, it can be provided involuntarily. The patient's life is always considered worth protecting and talk of suicide is considered a plea for help. The assisted-suicide competency approach agrees with the above underlying assumptions for all patients who are judged to have more than six months to live. Once patients are judged to have less than six months

to live, however, they are treated differently. At this point, according to the competency model, not only does the clinician no longer have an obligation to treat the suicidal symptom as a cry for help and to protect the patient, the doctor actually has the right to help the patient in killing themselves. It is interesting in this case that the legality of using the assisted-suicide competency model turned on the crucial issue of how much time the patient might live, when that fact could not be accurately determined – he was given multiple prognoses of only six months to live and out lived all of them, the most recent one by nearly half a year. In total he lived more than two years beyond the initial predictions of rapid death.

This case demonstrates that the attempt to use competing or mixed paradigms can result in mentally ill patients being given lethal prescriptions in Oregon as they have in the Netherlands (1); but that fact would not have been revealed in the official statistics. Had Mr. Freeland taken his overdose, he would have only been listed in the state report as another patient who did not need to be referred for psychiatric evaluation. The fact that he had a pre-existing psychiatric disorder and previous suicide attempts would not have been revealed, because the Oregon Health Division (OHD), which is responsible for protecting the public by overseeing assisted suicide, does not ask such questions. OHD would have only gathered information from Doctor Reagan, the assisted-suicide doctor, who did not consider psychiatric consultation necessary. As it was, he was only listed in the statistics published March 6, 2003 (23) as a patient who obtained an overdose but did not take it.

This case where assisted-suicide drugs were actually prescribed is the only one for which medical and psychiatric records have been made available. Even with this information, many unanswered questions remain. Would the patient have killed himself with the lethal overdose had friends and volunteers not attempted to dissuade him? Did the involuntary hospitalization and mental health treatment prevent assisted suicide or even a homicide? Was this man, who may have had a character disorder along with depression, engaging in splitting and projective identification (10-12) to further polarize views of him? Were the doctors involved swept up in acting out a countertransference reaction to a character disordered patient's lethal projections? Or was this case simply one of poor medical care?

These and other questions concerning similar cases can only be answered more fully through systematic and careful, independent review of cases prospectively or, at least, by retrospective review of medical and psychiatric records. Such studies, including review by multiple clinicians with differing viewpoints of all psychiatric records with identifying data of assisted-suicide patients masked, have been proposed to OHD. OHD, however, has refused access even to masked records for any independent review. So the information available will remain based on OHD reports, which rely on the assisted-suicide doctors themselves, and on the records of individual patients who are willing to release their medical records independently. To date, Michael Freeland is the only person in over 250 cases prescribed overdoses to do so.

CONCLUSIONS

The legalization of doctor-assisted suicide in Oregon has resulted in the introduction of competing paradigms – the traditional clinical approach and the assisted-suicide competency model – for responding to suicidal thoughts and behaviors in seriously ill individuals. Careful examination of events leading up to the death of the only case in which assisted-suicide drugs were legally prescribed for which medical records are available demonstrates that different models were used by some clinicians and others attempted to mix models, resulting in a confused and confusing approach to a life threatening symptom. These competing models appear to be based on incompatible underlying assumptions about the value of protecting human life depending on predictions of how long a patient might live, a prediction which cannot be made accurately. We conclude that the attempt to mix models is confusing to both clinicians and patients and endangers seriously ill patients, particularly those with a history of pre-existing mental illness.

REFERENCES

1. Hendin H: Suicide, assisted suicide, and euthanasia, in Harvard Guide to Suicide Assessment and Intervention. Edited by Jacobs DG (San Francisco, Jossey-Bass), 1999, pp 540-560

2. Hamilton NG, Hamilton CA: Therapeutic response to assisted suicide request. Bull Menninger Clin 1999; 63:191-201

3. Hamilton NG: Suicide prevention in primary care. Postgraduate Med 2000;108:81-84

4. Ganzini L, Farrenkopf T: Mental health consultation and referral, in The Oregon Death with Dignity Act: A Guidebook for Health Care Providers. Edited by Haley K, Lee M (Portland, Oregon: Oregon Health Sciences University), 1998, pp 30-32

5. Lebowitz BC, Pearson JL, Schneider LS, et al.: Diagnosis and treatment of depression in late life: consensus statement update. JAMA 1997;278:1186-1190

6. Beitbart W, Rosenfeld B, Pessin H, Kaim M, Funesti-Esch J, Galietta M, Nelson CJ, Brescia R: Depression, hopelessness, and desire for hastened death in terminally ill patients with cancer. JAMA 2000;284:2907-2911

7. Kissane DW, Clarke DM, Street AF: Demoralization syndrome – a relevant psychiatric diagnosis in palliative care. J Palliative Care 2001;17:12-21

8. Boehnlein JK, Beamer J, Goetz R, Hamilton NG, Pollack DA, Smith DM, Toenniessen LM: Report of the Committee on the Ethics of Physician-Assisted Suicide (Portland, Oregon: Oregon Psychiatric Association), September, 1996

9. Varghese FT, Kelly B: Countertransference and assisted suicide, in Countertransference Issues in Psychiatric Treatment. Edited by Gabbard GO, Review of Psychiatry, Vol. 18 (Washington DC: American Psychiatric Press), 1999, pp 85-116

10. Gabbard GO: An overview of countertransference: theory and technique, in Countertransference Issues in Psychiatric Treatment. Edited by Gabbard GO, Review of Psychiatry, Vol. 18 (Washington DC: American Psychiatric Press), 1999, pp 1-25

11. Hamilton NG: Self and Others: Object Relations Theory in Practice (Northvale NJ, Aronson), 1988

12. Hamilton NG: The Self and the Ego in Psychotherapy (Northvale NJ, Aronson), 1996

13. Emanuel E, Fairclough DL, Daniels ER, Clarridge BR: Euthanasia and physician-assisted suicide: Attitudes and experiences of oncology patients, oncologists, and the public. Lancet 1996;347:1805-1810

14. Block SD: Psychological considerations, growth, and transcendence at the end of life. JAMA 2001;285:2898-2905

15. Olevitch B: Protecting Psychiatric Patients and Others from the Assisted-Suicide Movement (Westport CT: Greenwood Publishing), 2002

16. Ganzini L, Leong GB, Fenn DS, Silva JA, Weinstock R: Evaluation of competence to consent to assisted suicide: Views of forensic psychiatrists. Am J Psychiat 2000;157:595-600

17. Kissane D: The contribution of demoralization to informed consent and end-of-life decision making. (Presented at this Symposium).

18. Hamilton CA: The Oregon report. Brainstorm NW, March 2000, pp 36-38

19. Foley K and Hendin H: The Oregon experiment, in The Case Against Assisted Suicide for the Right to End-of-Life Care. Edited by Foley K and Hendin H (Baltimore: Johns Hopkins Press), 2002, pp 144-174

20. Hamilton NG: Oregon's culture of silence, in The Case Against Assisted Suicide for the Right to End-of-Life Care. Edited by Foley K, Hendin H (Baltimore: Johns Hopkins), 2002, pp 173-191

21. Oregon Health Division: Sixth annual report on Oregon's Death with Dignity Act, Oregon Health Division, March 10, 2004, Worldwide web @ http://www.ohd.hr.state.or.us/chs/pas/ar-index.cfm)

22. Reagan P: Helen. Lancet 1999;359:1265-1267

23. Foley K, Hendin H: The Oregon report: Don't ask, don't tell. Hastings Center Report 1999;29:37-42.

24. Oregon Health Division: Fifth annual report on Oregon's Death with Dignity Act, Oregon Health Division, March 6,2003, Worldwide web @ http://www.dhs.state.or.us/news/2003news/2003-0305.html

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IN THE SUPREME COURT OF THE UNITED STATES

ALBERTO B. GONZALES, ATTORNEY GENERAL, ET AL.,
PETITIONERS
v.
STATE OF OREGON, et al.
ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* HEALTHLAW PROFESSORS IN SUPPORT OF RESPONDENTS FOR AFFIRMANCE OF THE COURT AND OPINION BELOW

Counsel for *Amici* Healthlaw Professors
Arthur B. LaFrance
Professor of Law
Lewis & Clark Law School
Portland, Oregon 97219
(503) 768-6627

Preliminary Statement

This Brief of Amicus Curiae Healthlaw Professors is submitted in support of the Respondent State of Oregon and with the consent of all the parties. As in the Court below, Amici have limited their Brief to the practice, procedures and success of physicians and patients under the Oregon Death With Dignity Act. The facts analyzed in this Brief bear directly on Attorney General Gonzales' arguments in his Brief that assisting death is not "treatment in the public interest" with a "legitimate medical purpose, in the usual course of medicine." See Petitioner's Brief, p. 11-24.

The Amici Curiae submitting this Brief are healthlaw professors at American law schools. Each is listed in the Law and Medicine section of the Directory of American Law Schools, published by the Association of American Law Schools. They have published extensively in the field, including the leading casebooks in Healthlaw and Bioethics, as well as dozens of articles in legal and medical journals. In their teaching, they regularly deal with issues of patient autonomy, physician responsibility and healthcare at the end of life.

This Amicus Brief is filed in the hope it will be of assistance to this Court.

Amici Healthlaw professors note, as well, that they and their families – like most Americans – are aging. They may wish someday to urge their legislatures to adopt statutes like the Oregon Death with Dignity Act.

TABLE OF CONTENTS

BRIEF OF *AMICI CURIAE* HEALTHLAW PROFESSORS IN SUPPORT OF RESPONDENTS FOR AFFIRMANCE OF THE COURT AND OPINION BELOW 1

ADOPTION BY REFERENCE 1

INTRODUCTION 2

I. THE OREGON DEATH WITH DIGNITY ACT ASSURES SAFE, RESPONSIBLE HEALTHCARE DECISIONS BY TERMINALLY ILL OREGONIANS 4

A. The Death With Dignity Act Provides a Structure for Competent Healthcare Choices at the End of Life .. 4

B. Death with Dignity is Chosen Annually In Oregon By A Sizeable Group of Physicians and Patients. 6

C. Patients Choose Assisted Suicide for Thoughtful, Responsible Reasons 9

II. CONTINUING OVERSIGHT ASSURES EXTENSIVE PROTECTION FOR TERMINALLY ILL PATIENTS UNDER THE OREGON DEATH WITH DIGNITY ACT 11

A. Contemporaneous Recordkeeping Guides Patient and Physician At All Times 11

B. There Is No Evidence Of Imposition On Depressed Or Disabled Patients 14

C. Patients Do Not Suffer Needless Pain, Mishap or Harm under the Oregon Act 18

III THE OREGON DEATH WITH DIGNITY ACT GUARANTEES SOUND AND ETHICAL PRACTICE OF MEDICINE 21

A. The Oregon Act Extends Ample Respect For The Role And Ethics Of Physicians 21

B. Practice Under The Oregon Act Fits Within the Accepted Community Standards of Medicine ... 23

C. Under Oregon's Death With Dignity Act Physicians Practice Sound, Compassionate Medicine, Including Palliative Care 26

CONCLUSION 28

APPENDIX

AMICI HEALTHLAW PROFESSORS IN SUPPORT OF RESPONDENT STATE OF OREGON AND IN SUPPORT OF AFFIRMANCE 31

TABLE OF CASES AND AUTHORITIES

CASES:

Gonzales v. Raich, ____ U.S. ____, 2005 WL 1321358 (6/06/05) 18, 29

In Re Cruzan, 497 U.S. 261 (1990) 5

Oregon v. Ashcroft 368 F.3d 1118 at1123, 1124, 1126-1128 (9th Cir. 2004) 2, 3

Oregon v. Ashcroft, 192 F. Supp. 2d 1077 (D. Or. 2002) ... 2

Planned Parenthood v. Casey, 505 U.S. 833 (1992) 5

Washington v. Gluckberg, 521 U.S. 702 (1997) 25

FEDERAL STATUTES:

U.S.C § 823(f) 2

U.S.C. § 824(1)(4) 2

STATE STATUTES:

Or. Rev. Stat. § 127.800 ..... 4, 14

Or. Rev. Stat. § 127.800(12) 21

Or. Rev. Stat. § 127.800(2) and (4) 4, 21

Or. Rev. Stat. § 127.800(3) 5

Or. Rev. Stat. § 127.800(7) 5

Or. Rev. Stat. § 127.805. ..... 4, 5, 14

Or. Rev. Stat. § 127.810(1) 11

Or. Rev. Stat. § 127.815 ..... 21, 22

Or. Rev. Stat. § 127.815(1)(c)(4) 22

Or. Rev. Stat. § 127.815(1)(i) 5

Or. Rev. Stat. § 127.815(e) 6

Or. Rev. Stat. § 127.815(f)-(h) 22

Or. Rev. Stat. § 127.815(h)-(k) 22

Or. Rev. Stat. § 127.820 ..... 4, 23

Or. Rev. Stat. § 127.825. ..... 6, 14

Or. Rev. Stat. § 127.830 5

Or. Rev. Stat. § 127.835. ..... 5, 22

Or. Rev. Stat. § 127.840 ..... 5, 22

Or. Rev. Stat. § 127.845 ..... 5, 22

Or. Rev. Stat. § 127.850. 5

Or. Rev. Stat. § 127.855 12

Or. Rev. Stat. § 127.885 22

Or. Rev. Stat. § 127.885(4) 22

Or. Rev. Stat. § 127.897. ..... 5, 11

OTHER AUTHORITIES:

Black, Wallace, et al. *Physician-Assisted Suicide and Euthanasia in Washington State*, 275 JAMA 919, 921, 923, Table 1 (3/27/96) 24, 25

Chen, Hedberg et al., *Legalized Physician-Assisted Suicide in Oregon - The First Year's Experience*, 340 NEJM 577, 582, 579 (1999) 6, 7, 19, 27

deVries, *A Dutch Perspective: The Limits of Lawful Euthanasia*, 13 ANN HEALTH LAW 365 (2004) 21

Emanuel, Daniels et al., *The Practice of Euthanasia and Physician-Assisted Suicide in the United States*, 280 JAMA 507, 510-512, Table 2, Table 3 (8/12/98) 26

Ganzini and Lee, *Psychiatry and Assisted Suicide in the United States*, 336 NEJM 1824 (6/19/97) 15

Ganzini, Block, *Physician-Assisted Death – A Last Resort?* 346 NEJM 1663 (5/23/2002) 16, 17

Ganzini, Harvath et al, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEJM 582, 584-5, 586-7, 820-2, 347 (8/22/2002) 10, 15, 16, 18, 28

Ganzini, Johnston et al., *Attitude of Patients*, 338 NEJM 967, 970, 971 (10/1/98) 16, 17

Ganzini, Nelson et al, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEJM 557 (2/24/2000) .. 9, 26

Gorsuch, *The Legalization of Assisted Suicide and the Law of Unintended Consequences*, 2004 Wis. L. Rev. 1347, 1358-1371 20

Groenewoud, Van der Heide, et al., *Clinical Problems with the Performance of Euthanasia and Physician-Assisted Suicide in The Netherlands*, 342 NEJM 551 (2/24/2000) 20

Hedberg & Southwick, *Legalized Physician- Assisted Suicide in Oregon*, 2001, 346 NEJM 450, Table 1 (2/7/2002) 8

Lee, Nelson et al, *Legalizing Assisted Suicide – View of Physicians in Oregon*, 334 NEJM 310, 313 (2/1/96) .. 18, 25

Meier, Emmons et al., *A National Survey of Physician-Assisted Suicide and Euthanasia In the United States*, 338 NEJM 1193, 1196 (4/23/98) 18, 24

Miller, Rosenberg et al, *The Care of the Patient with Amyotrophic Lateral Sclerosis*, 52 Neurology 1311, 1323 (1999) 16

Recent Case 118 HARV. L.REV. 1321, 1377-8 (2004) 3

Seventh Annual Report (DOH 2005) . . 13, 17, 19, 20, 22, 23

Steinbrook, Robert, MD, *Physician-Assisted Suicide in Oregon – An Uncertain Future*, 346 NEJM 460 at 461 (Feb. 7, 2002) 28

Sullivan, Hedberg et al, *Legalized Physician-Assisted Suicides in Oregon - The Second Year*, 342 NEJM 598, 599, 600-602 (2/24/2000) 7

Sullivan, Hedberg, et al., *Legalized Physician-Assisted Suicide in Oregon, 1998-2000*, 344 NEJM 605 (2/22/2001) 8

Veldinle, et al, *Euthanasia and Physician-Assisted Suicide Among Patients with Amyotrophic Lateral Sclerosis in the Netherlands*, 346 NEJM 1638 (5/23/2002) 16

IN THE SUPREME COURT
OF THE UNITED STATES

No. 04-623

ALBERTO B. GONZALES,
ATTORNEY GENERAL, et al.,
PETITIONERS

v.

STATE OF OREGON, et al.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* HEALTHLAW PROFESSORS IN SUPPORT OF RESPONDENTS FOR AFFIRMANCE OF THE COURT AND OPINION BELOW[1]

ADOPTION BY REFERENCE

Amici hereby adopt Petitioners' Provisions Involved and Statement of Facts.

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[1] No individual or organization party to this action has authored or made any financial or other contribution to this Amici Curiae brief.

INTRODUCTION

The opinion in the trial court is reported as *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002). Judge Jones there enjoined the Attorney General of the United States from implementing his "directive" declaring that medications to assist suicide do not have a "legitimate medical purpose," and further that prescribing them may mean a physician's federal narcotics registration is "inconsistent with the public interest," under The Controlled Substances Act. 21 U.S.C § 823(f); see also § 824(1)(4).

Judge Jones' opinion was affirmed by the Ninth Circuit Court of Appeals. In an opinion by Judge Tallman, the Court held the Attorney General lacked authority to intrude into Oregon medical practices. While the opinion said the Court took "no position on the merits or morality of physician assisted suicide," *Oregon v. Ashcroft,* 368 F.3d 1118 at 1123 (9th Cir. 2004), the Court necessarily found the practice appropriate for state legislation. *Id.* at 1124. The Court also found the Attorney General was making "medical" judgments beyond his statutory authority, *Id.* at 1126-1128, and carefully noted that the Court was not implying that even the Secretary of Health and Human Services could "determine that physician assisted suicide constitutes an illegitimate medical practice." *Id.* at 1127, note 10. The dissent argued the Attorney General not only had authority to determine whether physician assisted suicide is properly the practice of medicine but, in fact, had

ruled correctly, in relying on the Office of Legal Counsel memorandum finding it is not. *Id.* at 1144-1146.

Thus, whether this Supreme Court accepts the view of the majority or dissent below, it must determine whether physician assisted suicide is properly the practice of medicine. *See, Recent Case*, 118 HARV.L.REV. 1321, 1377-8 (2004). To that end, this Amicus Brief presents research data: First, the Oregon Death with Dignity Act assures that terminally ill Oregonians may make responsible healthcare decisions at the end of life; secondly, systematic reporting and continuing oversight provide ample protection against abuse or imposition, particularly on disabled or depressed patients; and finally, the role of physicians under the Death With Dignity Act guarantees sound and ethical medical practices.

These propositions are central to this case. Attorney General Gonazles would revoke Oregon physicians' right to prescribe medications, based on "findings" that assisting suicide represents a danger to the health of Oregonians. The Attorney General is wrong. He made no such "findings," and there is no such danger. The research and data are to the contrary. Various *Amici* below argued that the Death With Dignity Act poses a risk to the poor, or poorly educated, or the disabled, or to incompetent, terminally ill Oregonians. Like the Attorney General, their arguments are grounded in ideology, not facts. This Brief summarizes the research they ignored.

I. THE OREGON DEATH WITH DIGNITY ACT ASSURES SAFE, RESPONSIBLE HEALTHCARE DECISIONS BY TERMINALLY ILL OREGONIANS

A. The Death With Dignity Act Provides a Structure for Competent Healthcare Choices at the End of Life

The genius of the Oregon Act is simple and straightforward. The Act simply provides that a "capable" adult "suffering from a terminal disease" may make a written request for "medication for the purpose of ending his or her life in a humane and dignified manner." Or. Rev. Stat. § 127.805.

The Act then provides, Or. Rev. Stat. § 127.800 *et. seq.*, that before a patient is qualified to proceed, a

> . . .consulting physician shall examine the patient and his or her relevant medical records and confirm in writing the attending physician's diagnosis that the patient is capable, is acting voluntarily and has made an informed decision." Or. Rev. Stat. § 127.820.

There are thus two fully licensed physicians involved in the process, an "attending" (having primary responsibility for treatment) and a "consulting" ("qualified by specialty or experience to make a professional diagnosis and prognosis"). Or. Rev. Stat. § 127.800(2) and (4).

The two physicians not only confirm the diagnosis and prognosis; they must also confirm the patient is "capable," that is, has the ability "to make and communicate health

care decisions to health care providers" Or. Rev. Stat. § 127.800(3). And the patient must have "voluntarily expressed his or her wish to die," Or. Rev. Stat. § 127.805; that is, it must be preceded by full information received from the attending physicians as to the diagnosis, prognosis, risks, probable results and "feasible alternatives." Or. Rev. Stat. § 127.800(7).

This emphasis on informed decisionmaking assures central constitutional values of autonomy recognized by this Supreme Court in *In Re Cruzan*, 497 U.S. 261 (1990) and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992). This is facilitated by the Act providing a form: Request for Medication, to be filled out by the terminally ill patient. The form requires two witnesses, and the diagnoses of two physicians, but the consent only of the patient. Or. Rev. § 127.835. The patient shall indicate whether he or she has informed family or chosen not to do so. Or. Rev. Stat. § 127.897.

The prescribing physician is required, immediately prior to writing the prescriptions, to determine whether the patient has made an "informed decision." Or. Rev. Stat. § 127.815(1)(i), 127.830. The patient must have made two requests – one oral, one written – and repeat the oral request within fifteen days, Or. Rev. Stat. § 127.840, at which time a chance to rescind must be afforded. Or. Rev. Stat. § 127.845. A prescription for life-ending medication(s) may not be issued sooner than fifteen days after initial oral request. Or. Rev. Stat. § 127.850.

A patient may be referred for counseling, Or. Rev. Stat. § 127.815(e), if appropriate, pursuant to Or. Rev. Stat. § 127.825. The counselor must then determine the patient is not suffering from a "psychiatric or psychological disorder or depression causing impaired judgment." As noted later in this Brief, See Part II C., about 20% of requesting patients are referred on suspicion of depression and virtually none receives a life-ending prescription.

In essence then, Oregon law leaves to the competent, well informed, terminally ill patient a choice, but surrounds the patient with safeguards and safety nets. The experience of the past seven years demonstrates the success of this structure.

B. <u>Death with Dignity is Chosen Annually In Oregon By A Sizeable Group of Physicians and Patients.</u>

In Oregon, during the first year of the Death With Dignity Act, 23 people received prescriptions and 15 died after taking them. Their median age was 69. They were similar to "control" patients in most respects (sex, race, education, insurance, concern for finances), except the "case" patients had a greater concern about loss of autonomy and bodily functions. At death, 21% of the case patients and 84% of the controls were completely disabled. Chen, Hedberg et al., *Legalized Physician-Assisted Suicide in Oregon - The First Year's Experience*, 340 NEJM 577 (1999). There was no evidence to support fears that assisted suicide would be forced on patients who were

"poor, uneducated, uninsured or fearful of the financial consequences." *Id.* at 582.

During 1998, the second year of the Death With Dignity Act, 24 patients in Oregon received prescriptions. Sixteen died after ingesting the medication. Sullivan, Hedberg et al, *Legalized Physician-Assisted Suicides in Oregon - The Second Year*, 342 NEJM 598 (2/24/2000). They were similar demographically to those who died in the first year. Some 63% had end stage cancer and 78% were in a hospice program. *Id.* at 599.

Three or more reasons were discussed by 7 of 16 patients: loss of autonomy, an inability to enjoy life's activities, and inadequate control of pain. None mentioned cost of treatment or prolonging life as a concern. 342 NEJM at 600-602. The patients' reasons were confirmed by physicians and family members, although family members reported the patients had additional reasons, including a desire to control circumstances of death and fear of coma and respiration problems:

> Many family members emphasized that the patient wanted to have control over how he or she died . . . Family members expressed profound grief over their loss. However, mixed with this grief was great respect for the patient's choice. One man said about his wife of almost 50 years, "She was my only girl; I didn't want to lose her . . . but she wanted to do this." *Id.* at 603.

During the year 2000, the third year of the Oregon Act, 39 prescriptions were written and of these, 26 died after

taking the medication. The reasons and demographic characteristics remained the same (except that in 2000 more were married), and were identical to the 6981 Oregonians who died of similar diseases. As their educational level increased, so did the likelihood of choosing assisted suicide. Sullivan, Hedberg, et al., *Legalized Physician-Assisted Suicide in Oregon, 1998-2000,* 344 NEJM 605 (2/22/2001). As previously, the diagnosis was cancer in 3/4 of the deaths. The physician was present for half of the deaths and the patient died at home (including hospice) in 90% of the cases. *Id.* at Table 1.

In 2001, 33 physicians in Oregon wrote 44 prescriptions. Death from ingestion came to 19; 14 died of the underlying diseases. The demographic characteristics and motivations remained the same. Twenty patients died at home; physicians were present while nine took the medication. Complications (vomiting) were noted in only one case. Hedberg & Southwick, *Legalized Physician-Assisted Suicide in Oregon, 2001*, 346 NEJM 450 (2/7/2002), Table 1.

The Death with Dignity Act has come to enjoy stable acceptance and support over the past seven years. As the Seventh Annual Report of the Oregon Department of Human Services summarized in March of this year:

> In 2004, 40 physicians wrote a total of 60 prescriptions for lethal doses of medication, the first decrease in the annual total of prescriptions written since PAS became legal in Oregon. In 1998, 24

prescriptions were written, followed by 33 in 1999, 39 in 2000, 44 in 2001, 58 in 2002, 68 in 2003, and 60 in 2004. Thirty-five of the 2004 prescription recipients died after ingesting the medication. Of the 25 recipients who did not ingest the prescribed medication in 2004, 13 died from their illnesses, and 12 were alive on December 31, 2004. In addition, two patients who received prescriptions during 2003 died in 2004, after ingesting their medication, giving a total of 37 PAS deaths in 2004.

Although five fewer patients ingested lethal medication in 2004 compared to 2003, the trend has been upward since legalization. Paralleling the upward trend in the number of deaths are the ratios of PAS deaths to total deaths. In 1998 there were 5.5 PAS deaths per every 10,000 total deaths, followed by 9.2 in 1999, 9.1 in 2000, 7.0 in 2001, 12.2 in 2002. 13.6 in 2003, and an estimated 12/10,000 in 2004 (page 4).

The Oregon Act is thus working fairly and well. There are safeguards to assure this will continue.

C. <u>Patients Choose Assisted Suicide for Thoughtful, Responsible Reasons</u>

A 1999 survey of 4500 Oregon physicians found no instances of imposition or discrimination based on disability, poverty or education. Ganzini, Nelson et al, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEJM 557 (2/24/2000). The authors concluded:

> There is concern that with the legalization of assisted suicide, women, poor persons, and those who are members of ethnic or racial minority groups may request assistance with suicide because of inadequate social support or lack of access to health care. . .More than a third of the patients requested assistance with suicide because they perceived themselves as a burden to others, but only three of these patients received prescriptions for lethal medications, *suggesting that the physicians were reluctant to accede to requests for assistance under these circumstances.* (emphasis supplied).

A survey in 2001 of hospice nurses and social workers revealed important dimensions of the practice of assisted death under the Oregon Act. Ganzini, Harvath et al, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEJM 582, 584-5 (8/22/2002):

> According to the hospice nurses, the most important reasons for requesting assistance with suicide, among patients who received prescriptions for lethal medications, were a desire to control the circumstances of death, a desire to die at home, the belief that continuing to live was pointless, and being ready to die (Table 2). *Depression and other psychiatric disorders, lack of social support, and concern about being a financial drain were, according to nurses, relatively unimportant.* (Fig. 1).

* * *

> Hospice social workers reported that the desire to control the circumstances of death, the wish to die at home, loss of independence or fear of such loss, and loss of dignity or fear of such loss were the most important reasons for requesting prescriptions for lethal medications; the median score for all these reasons was 5 on the 1-to-5 scale. *They ranked lack of social support and depression as the least important reasons; the median score for both was 1.* (emphasis supplied)

Perhaps the most significant statistic is that each year, about one-third of qualifying patients choose against taking the prescribed medication, evidencing the care and autonomy reserved to them by the Oregon law and medical practice.

II. CONTINUING OVERSIGHT ASSURES EXTENSIVE PROTECTION FOR TERMINALLY ILL PATIENTS UNDER THE OREGON DEATH WITH DIGNITY ACT

A. Contemporaneous Recordkeeping Guides Patient and Physician At All Times

The Death With Dignity Act requires an ample "paper trail" for documentation that the Act's requirements are observed and that patients' rights are protected. A Request for Medication must be witnessed by two people who attest the patient is "capable, acting voluntarily, and is not being coerced to sign the request." Or. Rev. Stat § 127.810(1); Or. Rev. Stat.§ 127.897. Importantly, the patient's request form recites the elements of the Act (disease, information,

request) and includes information concerning advice to the family, the right to rescind, and the possibility that death may take more than three hours.

Oregon also requires that an extensive medical record be kept be kept on each patient. Or. Rev. Stat. § 127.855. This includes documenting both oral and written requests "for medication to end his or her life in a humane and dignified manner." The medical record must document the attending and the consulting physicians' findings as to prognosis, diagnosis, and the patient's voluntariness, capabilities and informed decision." It must also include the outcome of counseling, the offer of rescission at the time of the second oral request, and "a notation of the medication prescribed." *Id.*

Oregon thus assures patients the safety afforded by both medical and governmental administrative oversight. The latter has thus far generated seven Annual Reports by the Oregon Department of Health. These may be found online at the Department website, www.ohd.hr.state.or.us/chs/pas/year 4/or-index.ht. The Reports also are published in the NEW ENGLAND JOURNAL OF MEDICINE, as indicated earlier in this Brief. Each Report is approximately twenty pages in length and is accompanied by tables, detailing the extent of activity under the Act and the characteristics of the patients who sought and received assistance in dying. The result is that records are not simply filed and ignored; rather, they are

collected, analyzed and the results reported in respected, peer-reviewed medical journals.

The Seventh Annual Report of the Oregon Department of Health summarized the reporting and oversight practices as follows:

> When a prescription for lethal medication is written, the physician must submit to DHS information that documents compliance with the law. We review all physician reports and contact physicians regarding missing or discrepant data. DHS Vital Records files are searched periodically for death certificates that correspond to physician reports. These death certificates allow us to confirm patients' deaths, and provide patient demographic data (e.g. age, place of residence, educational attainment).
>
> In addition, using our authority to conduct special studies of morbidity and mortality, DHS had conducted telephone interviews with prescribing physicians after receipt of the patients' death certificates. Each physician was asked to confirm whether the patient took the lethal medications. If the patient had taken the medications, we asked for information that was not available from previous physician reports or death certificates–including insurance status and enrollment in hospice. We asked why the patient requested a prescription, specifically exploring concerns about the financial impact of the illness, loss of autonomy, decreasing ability to participate in activities that make life enjoyable, being a burden, loss of control of bodily functions, inadequate pain control, and loss of dignity.

We collected information on the time to unconsciousness and death, and asked about any adverse reactions. Because physicians are not legally required to be present when a patient ingests the medication, not all have information about what happened when the patient ingested the medication. If the prescribing physician was not present, we accepted information they had based on discussions with family members, friends or other health professionals who attended the patients' deaths. We also accepted information directly from these individuals. We did not interview or collect any information from patients prior to their death. In lieu of the telephone interview, physicians had the option of printing the questionnaire from our web site . (p. 10).

B. <u>There Is No Evidence Of Imposition On Depressed Or Disabled Patients</u>

The Oregon Death With Dignity Act, Or. Rev. Stat. § 127.800 *et seq*., has a number of protections to assure against abuse and overreaching. For example, it specifically provides that "No person shall qualify ... solely because of age or disability." Or. Rev. Stat. § 127.805. Also, any person who may be "suffering from a psychiatric or psychological disorder or depression causing impaired judgment" must be referred for counseling and cannot receive life-ending medication. Or. Rev. Stat. § 127.825. As noted above, a second opinion is required, and an extensive informed consent process is required as well.

Critics of the Oregon practice argue that it puts at risk vulnerable patients, such as those depressed or disabled.

This is a legitimate concern, but not supported by the facts. The danger that a terminally ill patient may be depressed is substantial; the requirement of a clinical evaluation – as a safeguard – is thus very important. *See* Ganzini and Lee, *Psychiatry and Assisted Suicide in the United States*, 336 NEJM 1824 (6/19/97). The seven Annual Reports are strikingly consistent: among patients receiving life-ending medication, there is little evidence of depression.

A survey of 545 hospice nurses and social workers clearly showed that patients clinically depressed were screened out of assisted death. Ganzini, Harvath et al, 347 NEJM at 582, 586:

> Outside of Oregon, one of the most consistent findings in studies of seriously or terminally ill patients is that depression increases the likelihood of a preference for hastening death. According to a survey of physicians in Oregon, *20 percent of patients who requested a prescription for lethal medication were depressed, though no depressed patients received prescriptions.* Hospice social workers have expertise in evaluating mood disorders in terminally ill patients. In our study, hospice social workers rated depression as *one of the least important of all 21 possible reasons* for requesting assistance with suicide among patients who received prescriptions for lethal medications.
>
> • • • •
>
> Our results suggest that *enrollment in a hospice program may offer additional protection.* Most requests for assistance with suicide that are

> made by patients enrolled in hospice programs are discussed with coworkers, often at interdisciplinary conferences. Many such patients are evaluated by clinical social workers with expertise in end-of-life care.

Ganzini, Harvath, 347 NEJM at 586-7. (emphasis supplied)

As with depression, critics of assisted suicide argue that patients with disabilities may be victimized by statutes like Oregon's. There is no evidence to support that view. The disability advocates are most often concerned with amyotrophic lateral sclerosis (ALS, Lou Gehrig's Disease). ALS patients, at least within six months of death, favor – and are excellent candidates for – assisted death. A study of 100 patients by Ganzini, Johnston et al., *Attitude of Patients*, 338 NEJM 967 (10/1/98) found 55% would consider assisted suicide. In The Netherlands from 1944 to 1999, 35 patients out of 203 with ALS chose euthanasia and 6 chose assisted death. Veldinle, et al, *Euthanasia and Physician-Assisted Suicide Among Patients with Amyotrophic Lateral Sclerosis in the Netherlands*, 346 NEJM 1638 (5/23/2002).

In Oregon, 56% of patients with ALS said they would consider assisted suicide and 44% said they would request a prescription, if legal. Miller, Rosenberg et al, *The Care of the Patient with Amyotrophic Lateral Sclerosis*, 52 Neurology 1311, 1323 (1999). In Oregon 5% of all deaths from ALS were from assisted suicide, compared with 0.4% with cancer. Ganzini, Block, *Physician-Assisted Death – A Last Resort?* 346 NEJM 1663 (5/23/2002). Reasons included "loss of autonomy, control, independence, and the ability to pursue pleasurable activities." *Id.*

The most recent study and report by the Oregon Department of Health noted that the demography of patients using the statute did not support fears of imposition or discrimination. A higher level of education was associated with PAS. Oregonians with a bachelor's degree were 8.3 times as likely to use PAS; The type of terminal illness was a strong predictor of usage – the highest being for ALS, HIV/AIDS and malignant neoplasms. Seventh Annual Report, p. 13 (2005). This suggests a rational process where patients are making thoughtful choices.

Perhaps the most significant protection for the terminally ill patient - disabled or not - comes from family. Caregivers of ALS patients usually agreed (73%) with the patients' view on assisted suicide. Ganzini, Johnston, 338 NEJM at 971. Caretakers objecting did so chiefly on religious grounds. *Id.* The task of caregiver is daunting – some 34% lost income or quit work as a result of caretaking or in order to caretake. For many, personal plans and social lives suffered. *Id.* at 970-971. The authors found the care givers' attitudes toward assisted suicide were not influenced by these factors, or by fatigue or finance or perception of suffering. During 2004, all patients but one died at home; 89% were enrolled in hospice care. Seventh Annual Report, p. 14 (2005).

In sum, the Death with Dignity Act provides a structure and process for safe end of life healthcare. And it does so consistent with the medical profession's ethics.

C. Patients Do Not Suffer Needless Pain, Mishap or Harm under the Oregon Act

Concern has been expressed that the *mechanics* of dying might be hazardous, producing errors or horrific consequences, such as comas. The fear is unfounded. 78% of the people who died from assisted suicide between 1998 and 2001 did so in safe hospice setting. Ganzini, Harvath, 347 NEJM 582 (8/22/2002). In a national survey, the medications commonly used for assisting death have been opioids and barbiturates, with potassium chloride being used for some injections. Meier and Emmons, 338 NEJM at 1196. In an Oregon survey, the drugs specified included barbiturates, narcotics, metabolic poisons, tricyclic antidepressants, alone or in combination with benzodiazepines, alcohol, cardiac medications, as muscle relaxants, all well-understood, commonplace medications.[2] Lee, Nelson et al, 334 NEJM at 313.

According to the most recent Department of Health Report:

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[2] In contrast, the substance (marijuana) banned by Congress in *Gonzales v. Raich*, ____U.S. ____, 2005, W: 132, 1358 (6/6/05) had *no* legal medical use. Here, the federal challenge is not as to the substances, but the medical practices in using them to assist the terminally ill.

> During 1998-2003 secobarbital was the lethal medication prescribed for 89 of the 171 patients (52%). During 2004, all lethal medications prescribed under the provisions of the DWDA were barbiturates. In 2004, 25 patients (68%) used pentobarbital and 12 patients (32%) used secobarbital. Since the DWDA was implemented, 49% of the PAS patients used secobarbital, 50% used pentobarbital and 2% used other medications (three used secobarbital/ amobarbital and one used secobarbital and morphine). Seventh Annual Report, p. 14 (ODOH 2005).

The average time of death was 26 minutes for the 15 people taking medications during the first year of the Oregon Act. No complications were reported. Chen, Hedberg et al, 340 NEJM at 579. During the second year, 27 patients died within 4 hours, the longest required 26 hours (having ingested only 2/3 of a dose). In the third year, the process remained largely the same: 20% to 30% referred for psychiatric evaluation, 30 minutes from ingestion to death, death at home in 90% of cases, with the physician present in 50%, and no complications (other than one instance of vomiting).

The latest State Report stated that:

> During 2004, physicians reported that three patients experienced complications: two patients vomited a small amount of the medication, one of whom died 15 minutes after ingestion and the other 45 minutes after ingestion. A third patient drank one-third of the prescribed medication and vomited, dying 31 hours later.

> Three patients fell into unconsciousness after having consumed one-half of the prescribed medication, with death occurring 30 minutes, 2.5 hours, and 7.5 hours after ingestion. Another patient said the lethal medication had a "bad taste" and quit after consuming 750 mg of pentobarbital; this patient died 12 hours later. One patient who ingested the entire dose of lethal medication died 19.5 hours after taking it.
>
> None of the patients regained consciousness after ingesting the lethal medication nor were emergency medical services called. Seventh Annual Report, p. 15 (2005).

Reports under the Oregon Act reflect far fewer complications than found in The Netherlands, in part – perhaps – because Oregon has benefitted from the Dutch experience and, unlike The Netherlands, does not employ euthanasia. Two studies in the 1990s in The Netherlands, encompassing 535 cases of euthanasia and 114 cases of assisted suicide, found problems of complication and completion. Groenewoud, Van der Heide, et al., *Clinical Problems with the Performance of Euthanasia and Physician-Assisted Suicide in The Netherlands*, 342 NEJM 551 (2/24/2000).

In addition, the Oregon practice is grounded in positive law, clearly authorizing and regulating physician assisted suicide, while protecting the rights of patients. See, most recently, Gorsuch, *The Legalization of Assisted Suicide and the Law of Unintended Consequences,* 2004 Wis. L.

Rev. 1347, 1358-1371; deVries, *A Dutch Perspective: The Limits of Lawful Euthanasia*, 13 Ann Health Law 365 (2004).

III THE OREGON DEATH WITH DIGNITY ACT GUARANTEES SOUND AND ETHICAL PRACTICE OF MEDICINE

A. The Oregon Act Extends Ample Respect For The Role And Ethics Of Physicians

The Oregon Death With Dignity Act requires the concurrence of at least two fully licensed physicians. One must be the attending physician, with primary care responsibilities. The other is "consulting," with enough expertise to make a "diagnosis and prognosis regarding the patient's disease." Or. Rev. Stat. § 127.800(2) and (4). That relationship guarantees two opinions, employing the "second opinion" so commonplace and widely recommended in medicine.

The provisions of the Death With Dignity Act concerning informed decision or consent, Or. Rev. Stat. § 127.815, are also well understood, commonplace predicates of the physician-patient relationship. And the diagnosis of a "terminal disease" is well within the limits of the physicians' practice and specialties, that the patient has "an incurable and irreversible disease that has been medically confirmed and will within reasonable medical judgment, produce death within six months." Or. Rev. Stat. § 127.800(12).

It is certainly true that Oregon's Act is detailed in mandating the elements of care in an end-of-life situation. The physician shall recommend notification of next of kin and arranging for another person to be present for the death event (and not taking the medication in a public place). Or. Rev. Stat. § 127.815(f)-(h), § 127.835. The Act also charges the physician to inform the patient about rescission, see Or. Rev. Stat. § 127.840, 845 to assure it truly is an informed decision, and "to ensure that all appropriate steps are taken . . . prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner." Or. Rev. Stat. § 127.815(h)-(k).

But none of these mandates is intrusive. Moreover, nothing in these requirements overrides or impinges upon the physician's simple, untrammeled right to decline to participate at all. See Or. Rev. Stat. § 127.885(4). Indeed, the provisions of Or. Rev. Stat. § 127.815, simply provide a careful checklist for good practice, which will then assure immunity from liability. Or. Rev. Stat. § 127.885.

In 2004, the average physician-patient relationship involving PAS was twelve weeks. This assured detailed, thoughtful caregiving by the physician involved. Seventh Annual Report, p. 14 (2005).

Importantly, the attending physician need not be directly involved in the death event. He or she may issue the medication directly, or send the prescription to a pharmacist for dispensing.Or. Rev. Stat.§127.815(1)(c)(4).

And the consulting physician, of course, is required only to confirm the diagnosis. Or. Rev. Stat. § 127.820. Thus, there is no requirement under Oregon statute that either a physician directly bring about death or even be present at the time.

B. <u>Practice Under The Oregon Act Fits Within the Accepted Community Standards of Medicine</u>

The argument that assisted death is not "medicine" or consistent with the "ends" of medicine must be tested against the actual practices of physicians and expectations of patients. The 2005 Report (p. 14) found:

> The prescribing physicians of patients who used PAS during 2004 had been in practice a median of 22 years (range 6-36). Their medical specialties included: family medicine (57%), oncology (22%), internal medicine (8%), and other (14%).
>
> Most physicians (70%) who wrote prescriptions for lethal medication during 2004 wrote a single prescription. Of the 40 physicians who wrote prescriptions in 2004, 28 wrote one prescription, nine wrote two prescriptions, one wrote three prescriptions, another wrote four prescriptions, and one wrote seven prescriptions.
>
> During the first three years after the legalization of PAS, physicians were present at the patient's ingestion of lethal medication half or more of the time. During 2004, the prescribing physician was present 16 percent of the time (6 of 37

patients). Among the remaining 31 patients, 25 (81%) ingested the medication in the present of another healthcare provider/volunteer.

During 2004, one case involving three issues was referred to the Oregon Board of Medical Examiners. This case involved failure to submit a physician survey in a timely manner, filing an incomplete Attending Physician's Compliance Form, and witnessing of signatures on a patient request form.

Physicians nationally now regularly receive requests for assistance in dying. *See*, Meier, Emmons et al., *A National Survey of Physician-Assisted Suicide and Euthanasia In the United States,* 338 NEJM 1193 (4/23/98). Ten medical specialties (e.g. cardiology, geriatrics, neurology) were identified as likely to encounter dying patients. Of those responding, 36% said – if legal – they would hasten death by medication, 24% by injection. Nearly 30% had received such requests from patients. And 20% had complied.

Patient requests for assisted death are not rare, even in states where it is illegal, such as Washington State. A survey by Black, Wallace, et al. *Physician-Assisted Suicide and Euthanasia in Washington State,* 275 JAMA 919 (3/27/96) produced 828 responses, with 12% (99) of the physicians reporting a request during the preceding year. Of 156 patients making requests, 38 (24%) received prescriptions and 21 died as a result. Of 58 patients who requested euthanasia, 14 (24%) received parenteral mediation and died. *Id*. The physicians had a variety of specialties, including oncology, family practice and

internal medicine, *Id.* Table 1. In the majority of cases, diagnoses were terminal cancer or AIDS. *Id*. at 921. The Washington State study is especially significant because Washington is often compared to Oregon, but assisted suicide is illegal there, a ban upheld by this Supreme Court in *Washington v. Gluckberg*, 521 U.S. 702 (1997). The fact that assisted death nevertheless persists and is widespread is compelling evidence of the profession's view of itself and its obligations to the public. Black and Wallace attempted to explore this deep-rooted commitment by in-depth interviews with ten physicians. Four "themes" emerged: physicians hesitate to assess nonphysical suffering; a request changed the nature of the relationship; granting a request was part of the obligation of compassionate care; legal constraints inhibit open discussion with colleagues. 275 JAMA at 923.

The views of Oregon physicians as to assisted suicide were ascertained and evaluated in 1995, shortly after passage of the Death With Dignity Act in 1994. *See*, Lee, Nelson et al, *Legalizing Assisted Suicide – View of Physicians in Oregon*, 334 NEJM 310 (2/1/96). Of those responding 81% had cared for at least one terminally ill patient. Importantly, 71% believed such patients have a right to commit suicide, and 66% believe physician-assistance would be ethical. During the preceding year, 21% had been asked for life-ending medication, 7% complied, half of the patients took the medication.

It is important to emphasize that Oregon does not make the physician the agent of death. Most are not even present at the time of death. The choice and act remain with the

patient, consistent with accepted professional principles on autonomy and beneficence.

C. Under Oregon's Death With Dignity Act Physicians Practice Sound, Compassionate Medicine, Including Palliative Care

In a survey in 1999 of 4,000 Oregon physicians, 144 had received a total of 221 requests for life ending medication. 75% of those patients had a life expectancy less than six months; 20% had symptoms of depression; none received a prescription. Importantly, *palliative measures – including pain control and hospice – were undertaken for 68 patients, and nearly half changed their minds.* Ganzini, Nelson et al, *Physicians' Experiences with the Oregon Death With Dignity Act*, 342 NEJM 557 (2/24/2000). Equally significant, *physicians grant only 1 in 6 requests for lethal medication. Id.*

In one study of 355 oncologists (72.6% response rate), 56 (15.8%) reported participating in assisted suicide or euthanasia. Emanuel, Daniels et al., *The Practice of Euthanasia and Physician-Assisted Suicide in the United States*, 280 JAMA 507 (8/12/98). Overall, they adhered to three main safeguards: (1) requiring repeated requests, (2) ensuring the patient was experiencing extreme pain, and (3) consulting with a colleague. Table 2, *Id.* at 510. In all cases, the patients with pain were receiving palliative care. *Id.*, Table 3. Over half of the oncologists found comfort in assisting, but nearly 40% feared prosecution. *Id.* at 510-511. The authors were concerned with lack of consistent adherence to safeguards and inconsistency in categorizing cases and treatment, *Id.* at 511-512, as well as errors in the administration of the medicine. *Id.* at 512. These concerns

are legitimate, and serve to underscore the value of the safeguards provided and required in the Oregon statute.

Palliative care to relieve pain is urged as an alternative to assisted suicide; some critics maintain its absence drives patients toward assisted death. In Oregon, during the first year under the Death with Dignity Act, the evidence was to the contrary. The same proportions of "case" patients and "control" patients had advance directives and were in hospice care. Chen, Hedberg et al, *Legalized Physician-Assisted Suicide in Oregon - The First Year's Experience*, 340 NEJM 577, 582 (2/18/99). Oregon ranks third in the nation for hospice admissions and among the top five in the use of morphine for pain. *Id.*

> Physicians in Oregon have referred an increased number of patients to hospice programs since 1994 and have made efforts to improve their knowledge of palliative care, according to a survey conducted in 1999.

****

Control of pain has received particular attention. Oregon ranks first among the states in use of morphine. Between 1997 and 2000, morphine use increased by about 50 percent in Oregon (Fig. 2). According to the Drug Enforcement Administration, per capita morphine consumption in Oregon was 4820 g per 100,000 people in 2000, as compared with 2770 g. per 100,000 people in the United States as a whole. In Oregon, substantive palliative interventions, such as control of pain or other symptoms, referral to a hospice program, consultation with another

> physician, or a trial of antidepressant medication, led about half of patients who were considering assisted suicide to change their minds.

Steinbrook, *Physician Assisted Suicide in Oregon*, 346 NEJM 460 at 461 (2/7/2002)

The compassionate care afforded in Oregon by assisted suicide involves the families as well as the patients: The survey of hospice social workers and nurses in Oregon reflected the following, concerning attitudes of families:

> Eighty-five percent of hospice nurses reported that all close family members of patients who received a prescription for a lethal mediation knew about it, and 90 percent said that all or most of the family members accepted the patient's decision to pursue assisted suicide. (Table 3). Seventy-seven percent of nurses and social workers reported that they had discussed the patient's request for a prescription with the family. Overall, families of patients who receive prescriptions for lethal medications were more accepting of and prepared for the patient's death, although they were somewhat more likely to be distressed than were the family members of other hospice patients.

Ganzini, Harvath et al, 347 NEJM at 586.

CONCLUSION

The facts are these: In Oregon, competent patients, for competent reasons, when faced with a terminal illness, may wish to choose the time, place and manner of death. Oregon has assured its citizens they may do so, safely and

with dignity. And, in choosing to assist death, physicians are practicing good medicine. This is the well-grounded position of the electorate and citizenry of Oregon, who have twice authorized the Oregon Death with Dignity Act by state-wide referenda.

This medical system has now worked safely and compassionately for seven years, helping hundreds to obtain death with dignity. There is no evidence of discrimination against the poor, the disabled, the ill educated, the depressed. Instead, careful monitoring establishes that Oregon annually dozens of enables capable, thoughtful citizens to face their ends with autonomy and dignity. The physicians who assist their patients are themselves free to practice medicine consistent with their medical and personal ethics, prescribing familiar medications regularly prescribed for routine medical purposes.

This case is thus in sharp contract to *Gonzales v. Raich*, ____ U.S. ____, 2005 WL 1321358 (6/06/05), where the medicinal substance (marijuana) had been declared by Congress to be illegal and of no medicinal value. The patients only argument was that this exceeded Congress' Commerce Clause authority. Here, the physicians and patients are using medications routinely and regularly prescribed for medical purposes. Congress has not banned

them, and the Attorney General has no authority himself to ban sound medical practice using them.

Respectfully Submitted
Amici HealthlLaw Professors

By Arthur B. LaFrance 6/10/05

June 10, 2005

Arthur B. LaFrance
Attorney at Law
Professor of Law
Lewis and Clark Law School
Portland, Oregon 97219

APPENDIX
AMICI HEALTHLAW PROFESSORS IN SUPPORT OF RESPONDENT STATE OF OREGON AND IN SUPPORT OF AFFIRMANCE

Lee Albert
State Univ. of New York at Buffalo
School of Law
John Lord O'Brian Hall, North Campus
Buffalo, New York 14260

Elizabeth Bartholet
Morris Wasserstein Professor of Law
Harvard University Law School
Cambridge, MA 02138

Richard Bonnie
John S. Battle Professor of Law & Director,
Institute of Law, Psychiatry and Public Policy
University of Virginia School of Law
580 Massie Road
Charlottesville, VA 22903

Ralph Brill
Professor of Law
Chicago-Kent College of Law
Illinois Institute of Technology
565 West Adams Street
Chicago, IL 60661-3691

Scott C. Burris
Professor of Law
Temple University
James E. Beasley School of Law
1719 N. Broad Street
Philadelphia, PA 19122

Steve Calandrillo
Assoc. Professor of Law
University of Washington School of Law
William H. Gates Hall
Box 35320
Seattle, WA 98195-3020

Kathy L. Cerminara
Assoc. Professor of Law
Nova Southeastern Univ.
Shepard Broad Law
Center
3305 College Avenue
Ft. Lauderdale, FL 33314

Marguerite Chapman
Associate Professor of Law
The University of Tulsa
College of Law
3120 East 4th Place
Tulsa, OK 74104

Phyllis Coleman
Professor of Law
Nova Southeastern Univ.
Shepard Broad Law Center
3305 College Avenue
Ft. Lauderdale, FL 33314

Judith Daar
Professor of Law
Whittier Law School
3333 Harbor Blvd.
Costa Mesa, CA 92626

Jane Friedman
Professor of Law
Wayne State University
Law School
471 W. Palmer
Detroit, MI 48202

Kenneth Gatter, MD, JD
Department of Pathology
L471
Oregon Health Sciences
University
3181 SW Sam Jackson
Park Road
Portland, OR 97201

Sharonna Hoffman
Assoc. Professor of Law
Case Western Reserve
Univ. Law School
11075 East Blvd
Cleveland, OH 44106

Timothy Jost
Professor of Law
Washington & Lee Univ.
School of Law
Sydney Lewis Hall
Lexington, VA 24450

Joan Krause
Assoc. Professor of Law
University of Houston
Law Center
100 Law Center
Houston, TX 77204-6060

Craig M. Lawson
Professor of Law
University of Nebraska
College of Law
103 McCollum Hall
42nd & Fair Sts.
Lincoln, Nebraska 68583

Alan Meisel
Professor of Law
University of Pittsburgh
School of Law
3900 Forbes Avenue
Pittsburgh, PA 15260

Frances Miller
Professor of Law
Baylor University
School of Law
765 Commonwealth
Avenue
Boston, MA 02215

Rand Rosenblatt
Rutgers Univ. School of
Law
217 N. 5th Street
Camden, NJ 08102

Stacey Tovino
Visiting Professor
University of Houston
100 Law Center
Houston, TX 77204-6060

Kenneth R. Wing
Professor of Law
Seattle University School
of Law
900 Broadway
Seattle, WA 98122-4340

CERTIFICATE OF SERVICE

I certify that on June 10, 2005, I directed the original and forty copies of the *Amici Curiae* Brief, together with the original consents of all parties to be filed with the Clerk, by overnight courier. I also directed that copies of the *Amici Curiae* Brief be sent by United States Postal Service to the following at the following addresses:

Paul Clemens
Acting Solicitor General
office of the Solicitor General
450 Pennsylvania Avenue
Washington, D.C.20530-0001

Nicholas Van Aelstyr
Heller Ehrman White & McAuliffe, LLP
333 Bush Street
San Francisco, CA 94104-2878

Eli D. Stutsman
Attorney at Law
621 SW Morrison Street
American Bank Bldg., 13th Floor
Portland, Oregon 97205

Kathryn L. Tucker
Legal Director
Compassion in Dying Federation
1201 3rd Avenue
40th Floor
Seattle, Washington 98101-3000

Mary Williams
Solicitor General
Department of Justice
State of Oregon
1162 Court Street NE
Salem, OR 97301

Arthur B. LaFrance

ARTHUR B. LAFRANCE 6/10/05
Professor of Law
Lewis and Clark Law School
Counsel for *Amici Curiae*

No. 04-623

In the Supreme Court of the United States

ALBERTO R. GONZALES, Attorney General, et al,

Petitioners,

v.

STATE OF OREGON, et al,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR RESPONDENT STATE OF OREGON

HARDY MYERS
Attorney General of Oregon
PETER SHEPHERD
Deputy Attorney General
*MARY H. WILLIAMS
Solicitor General
ROBERT M. ATKINSON
Assistant Attorney General
400 Justice Building
Salem, Oregon 97301-4096
Phone: (503) 378-4402
Counsel for Respondent
State of Oregon

*Counsel of Record

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

TABLE OF CONTENTS

Page

Question Presented..... i

Statement..... 1

Summary of Argument 10

Argument 12

I. The U.S. Attorney General's threatened action would nullify the DWDA..... 17

A. The DWDA does not merely "decriminalize physician assisted suicide." 18

B. The principles underlying the presumption against preemption apply here..... 20

II. The CSA does not itself prohibit the uses of controlled substances permitted by the DWDA, and it does not authorize the U.S. Attorney General to do so. 21

A. Neither the text of the CSA nor judicial interpretations of that text suggest that Congress intended to displace the States' traditional power to regulate medical practice, even when controlled substances are involved..... 21

1. The text generally and judicial interpretations..... 21

2. The "anti-preemption clause" 26

B. The CSA contains no clear statement of intent to displace state regulation of medicine. 27

1. Because the U.S. Attorney General's action here would displace traditional state authority, a clear statement is a condition precedent to that action or to *Chevron* deference. 30

2. The clear statement rule applies more broadly than petitioners acknowledge..... 31

3. The CSA reflects Congress's intent to respect the States' traditional role in regulating medical practice..... 34

C. A clear statement is required here to support the U.S. Attorney General's threat to displace the States' traditional regulation of medical practice. 38

D. A clear statement is required here to support the U.S. Attorney General's threat because it would push the boundaries of Congress's authority under the Commerce Clause. 42

III. The Court should reject this unprecedented attempt by an agency official to resolve a disputed issue of social and medical policy that is reserved to the States and should reemphasize the vital role State sovereignty plays in our federal system and the need for Congress to speak clearly when it intends to interfere with that role. 48

Conclusion 50

TABLE OF AUTHORITIES

Page

Cases Cited

Argentine Republic v. Amerada Hess Shipping, 488 U.S. 428 (1989)..... 27

California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316 (1997)..... 33

California Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272 (1987)..... 20

Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837 (1984)..... 11, 30, 31

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)..... 21

Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990)..... 40

Department of Revenue of Ore. v. *ACF Industries, Inc.*, 510 U.S. 332 (1994)..... 20, 38

Doe v. Bolton, 410 U.S. 179 (1973)..... 23

Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council, 485 U.S. 568 (1988)..... 30

ETSI Pipeline Project v. Missouri, 484 U.S. 495 (1988)..... 31

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)..... 31

Gade v. National Solid Wastes Management Ass'n., 505 U.S. 88 (1992)..... 29

Garcia v. San Antonio Metro. Transit Auth.,
469 U.S. 528 (1985) 28, 46

Geier v. American Honda Motor Co.,
529 U.S. 861 (2000) 35

Gonzales v. Raich,
545 U.S. ___,
125 S. Ct. 2195 (2005) 3, 4, 14, 15, 22, 41, 43-46

Gregory v. Ashcroft,
501 U.S. 452 (1991) 28, 30, 31, 32, 33, 34

Grinspoon v. Drug Enforcement Admin.,
828 F.2d 881 (1st Cir. 1987) 25

Hammer v. Dagenhart,
247 U.S. 251 (1918) 47

Hillsborough County v. Automated Medical Labs.,
471 U.S. 707 (1985) 30, 35, 38

Hisquierdo v. Hisquierdo,
439 U.S. 572 (1979) 33

Humphreys v. Drug Enforcement Admin.,
96 F.3d 658 (3rd Cir. 1996) 22

INS v. St. Cyr,
533 U.S. 289 (2001) 45

Jones v. United States,
529 U.S. 848 (2000) 20, 30, 33, 43, 46, 47

Linder v. United States,
268 U.S. 5 (1925) 23, 47

McCulloch v. Maryland,
4 Wheat. 316 (1819) 47

Medtronic Inc. v. Lohr,
518 U.S. 470 (1996) 26, 38, 39, 41, 42, 48, 49

Mississippi Band of Choctaw Indians v. Holyfield,
490 U.S. 30 (1989) 16, 17, 35

National Cable & Telecommunications Assn. v. Brand X Internet Services,
545 U.S. ___ (June 27, 2005) 31

New State Ice Co. v. Liebmann,
285 U.S. 262 (1932) 40

New York v. United States,
505 U.S. 144 (1992) 47

NLRB v. Action Automotive, Inc.,
469 U.S. 490 (1985) 27, 43

Perez v. United States,
402 U.S. 146 (1971) 43

Printz v. United States,
521 U.S. 898 (1997) 47

Raygor v. Regents of the University of Minnesota,
534 U.S. 533 (2002) 32

Retail Clerks v. Schermerhorn,
375 U.S. 96 (1963) 26

Rice v. Santa Fe Elevator Corp.,
331 U.S. 218 (1947) 28, 32, 33, 35

Robinson v. California,
370 U.S. 660 (1962) 47

Rush Prudential HMO, Inc. v. Moran,
536 U.S. 355 (2002) 33

Solid Waste Agency of Northern Cook Cty. v. Army Corps of Engineers,
531 U.S. 159 (2001) 17, 28, 30, 42, 43, 46

Touby v. United States,
500 U.S. 160 (1991) 4, 24

United States v. Bass,
404 U.S. 336 (1971) 20, 29, 32

United States v. Collier,
478 F.2d 268 (5th Cir. 1973) 23

United States v. Darby,
312 U.S. 100 (1941) 47

United States v. Five Gambling Devices,
346 U.S. 441 (1953) 46

United States v. Kahriger,
345 U.S. 22 (1953) 47

United States v. Lopez,
514 U.S. 549 (1995) 29, 30, 32, 43, 46, 47

United States v. Moore,
423 U.S. 122 (1975) 9, 22, 36

United States v. Morrison,
529 U.S. 598 (2000) 32, 46, 47

United States v. Rosen,
582 F.2d 1032 (5th Cir. 1978) 22

United States v. Rosenberg,
515 F.2d 190 (9th Cir.),
cert. denied, 423 U.S. 1031 (1975) 23

Vacco v. Quill,
521 U.S. 793 (1997) 40, 44

Washington v. Glucksberg,
521 U.S. 702 (1997) 6, 8, 9, 12, 13, 40

Whalen v. Roe,
429 U.S. 589 (1977) 38

Wickard v. Filburn,
317 U.S. 111 (1942) 44

Will v. Michigan Dept. of State Police,
491 U.S. 58 (1989) 29, 40

Constitutional and Statutory Provisions

5 U.S.C. §§ 551-559 5

7 U.S.C. § 2156(h) 26

15 U.S.C. § 78bb(a) 27

21 U.S.C. § 801 3

21 U.S.C. § 802(21) 4

21 U.S.C. § 811 4

21 U.S.C. § 811(a) 4, 24

21 U.S.C. § 811(a)(1)(A) 24

21 U.S.C. § 811(a)(1)(B) 24

21 U.S.C. § 811(b) 5, 24

21 U.S.C. § 811(c) 5

21 U.S.C. § 811(f) 6, 15

21 U.S.C. § 812 4

21 U.S.C. § 812(b)(1) 4

21 U.S.C. § 812(b)(2)(B) 25

21 U.S.C. § 821(f) (1970) 36

21 U.S.C. § 822(b) 4

21 U.S.C. § 823(a) 6

21 U.S.C. § 823(b) 6

21 U.S.C. § 823(d) 6

21 U.S.C. § 823(e) 6
21 U.S.C. § 823(f) 6, 36
21 U.S.C. § 824(a) 6
21 U.S.C. § 824(a)(4) 19
21 U.S.C. § 824(a)(4) (1984) 36
21 U.S.C. § 841(a)(1) 3, 21
21 U.S.C. § 844(a) 22
21 U.S.C. § 903 ..... 26, 35
30 U.S.C. § 955(a) 27
Or. Rev. Stat. §§ 127.800 through 127.995 1
Or. Rev. Stat. § 127.800(12) 2
Or. Rev. Stat. § 127.805 1
Or. Rev. Stat. § 127.810 1
Or. Rev. Stat. § 127.815 ..... 1, 2
Or. Rev. Stat. § 127.815(1)(j) 3
Or. Rev. Stat. § 127.815(c) 2
Or. Rev. Stat. § 127.820 ..... 1, 2
Or. Rev. Stat. § 127.825 2
Or. Rev. Stat. § 127.840 1
Or. Rev. Stat. § 127.855 3
Or. Rev. Stat. § 127.865 3
Or. Rev. Stat. § 163.125(1)(b) 18

Administrative Rules

21 C.F.R. § 1306.04 7
21 C.F.R. § 1306.04(a) (1971) 35

Other Authorities

Cass R. Sunstein,
Chevron Step Zero, 92 Va. L. Rev.
(forthcoming April 2006) 31

Oregon Department of Human Services,
Fifth Annual Report on Oregon's Death With Dignity Act (2003) 43

Oregon Department of Human Services,
Seventh Annual Report on Oregon's Death with Dignity Act (2005) 13, 19, 43, 45

Thomas W. Merrill & Kristin E. Hickman,
Chevron's Domain, 89 Geo. L. J. 833 (2001) 31

STATEMENT

Exercising its traditional power to regulate the practice of medicine, Oregon became the first state to authorize physicians to prescribe controlled substances to competent terminally ill adults to allow them to control the time, place, and manner of death. The question presented in this case is whether physicians acting in accordance with Oregon's law violate the Controlled Substances Act (CSA) or, in the alternative, whether the CSA authorizes the U.S. Attorney General to determine that they do.

1. a. In 1994, the people of Oregon enacted by initiative the Oregon Death with Dignity Act (DWDA).[1] The DWDA establishes tightly controlled procedures allowing physicians to prescribe Schedule II controlled substances to competent terminally ill adult patients in sufficient kind and quantity to permit the patient to control the time, place, and manner of death. Or. Rev. Stat. §§ 127.800 through 127.995. Or. Rev. Stat. § 127.805; App. to Pet. for Cert. 163a.

To comply with the DWDA, a patient must make an oral request to his or her attending physician and, after a 15-day waiting period, make a written request witnessed by at least two individuals. Or. Rev. Stat. § 127.810; § 127.840. Two doctors must determine that the patient is mentally capable, is "suffering from a terminal disease," and has voluntarily expressed a wish to accelerate the dying process. Or. Rev. Stat. § 127.805; § 127.815; § 127.820. A patient is "terminally ill" if the person has "an incurable and irreversible disease that has been medically confirmed and

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[1] In 1997, the Oregon legislature referred to the people a measure that would have repealed the DWDA. The repeal measure was rejected in the November 1997 election by 60% of the voters.

will, within reasonable medical judgment, produce death within six months." Or. Rev. Stat. § 127.800(12).

In addition to determining the patient's Oregon residence, the attending physician must also ensure that the patient has made an informed decision, which requires that the patient be advised of the medical diagnosis, the prognosis, the potential risks associated with the medications to be prescribed, the probable result of taking the medication, and the feasible alternatives, including comfort care, hospice care, and pain management. Or. Rev. Stat. § 127.815. The attending physician must refer the patient to a consulting physician "for medical confirmation of the diagnosis" and to verify that the patient is capable and acting voluntarily. Or. Rev. Stat. § 127.815(c); § 127.820. The consulting physician must "examine the patient and his or her relevant medical records and confirm, in writing" the diagnosis. Or. Rev. Stat. § 127.820. The attending and consulting physicians must refer the patient for counseling if either believes that the patient "may be suffering from a psychiatric or psychological disorder or depression causing impaired judgment." Or. Rev. Stat. § 127.825. Once a request from a qualifying patient has been properly documented and witnessed, and all waiting periods have expired, the attending physician may prescribe, but not administer, medication to enable the patient to end his or her life in a humane and dignified manner.[2]

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[2] The DWDA has been described as authorizing "physician assisted suicide." That description is potentially misleading inasmuch as neither the physicians who prescribe nor the pharmacists who dispense drugs under the DWDA may provide physical assistance to the patient. The term may be overbroad in another sense. To the extent that the dictionary describes "suicide" as taking one's own life, it might technically be accurate as applied to the DWDA. But the DWDA is available to only a very small subset of those who might choose to end their lives. Most significantly, as described above, it is available only to those whose death is predictably imminent. Moreover, it imposes stringent restrictions, foremost among them those dealing with mental competence and the concurrence of two physicians, on people who would take advantage of its provisions.

The DWDA immunizes physicians and pharmacists who act in compliance with its comprehensive procedures from state civil or criminal sanctions, and from any professional disciplinary action based on that conduct. The DWDA also requires the attending physician and other participating health-care providers to comply with medical documentation and reporting requirements. Or. Rev. Stat. § 127.815(1)(j); § 127.855; § 127.865.

b. In 1970, Congress enacted the CSA, 21 U.S.C. § 801 *et seq.*, Title II of the Comprehensive Drug Abuse Prevention and Control Act, to address the "perceived need to consolidate the growing number of piecemeal drug laws and to enhance federal drug enforcement powers[.]" *Gonzales v. Raich*, 545 U.S. ___, ___, 125 S. Ct. 2195, 2203 (2005). Because Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels, "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." 125 S. Ct. at 2203 (footnote omitted).

With the CSA, Congress created a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a)(1); *Raich*, 125 S. Ct. at 2203-04. The CSA categorizes all controlled substances into five schedules, based on their accepted medical uses, the potential for abuse, and their psychological

and physical effects on the body. 21 U.S.C. §§ 811, 812. Although Congress initially placed various substances on each of the five schedules, it also gave the U.S. Attorney General authority to add substances to or remove them from the schedules and to move them from one schedule to another if he follows the requisite procedures and makes the required findings. Schedule I substances, such as marijuana, have been determined to have no accepted medical use. 21 U.S.C. § 812(b)(1); *Raich*, 125 S. Ct. at 2204. All substances on Schedules II through V, including those prescribed by physicians under the DWDA, have accepted medical uses. Physicians, pharmacists, and other practitioners who dispense controlled substances must obtain a registration from the U.S. Attorney General.[3] Physicians may prescribe controlled substances only "in the course of professional practice or research," 21 U.S.C. § 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," 21 U.S.C. § 822(b).

To exercise his authority to schedule or reschedule substances, the U.S. Attorney General must follow a statutorily specified process. 21 U.S.C. § 811(a); *see Touby v. United States*, 500 U.S. 160, 162-63 (1991). He must first request a scientific and medical evaluation from the Secretary of Health and Human Services (Secretary), together with a

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[3] The CSA applies to "practitioners," which, in general terms, it defines to include physicians, dentists, veterinarians, scientific investigators, pharmacists, and others who are licensed by the United States or the jurisdiction in which they practice to distribute, dispense, or conduct research on or analysis of controlled substances. 21 U.S.C. § 802(21); App. to Pet. for Cert. 149a. For convenience, and because Oregon's law applies only to physicians and pharmacists, this brief generally refers only to physicians.

recommendation about whether the substance should be controlled. A substance cannot be scheduled if the Secretary recommends against it. 21 U.S.C. § 811(b). The CSA provides that "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters[.]" *Id.* Second, the U.S. Attorney General must consider eight factors, including the substance's potential for abuse, scientific evidence of its pharmacological effect, and the likelihood of dependence. 21 U.S.C. § 811(c). Third, the U.S. Attorney General must comply with the notice-and-hearing provisions of the Administrative Procedure Act (APA), 5 U.S.C. §§ 551-559, which permit comment by interested parties. 21 U.S.C. § 811(a).

In 1974, Congress made changes to the CSA to address treatment of addicts. In enacting the amendments, Congress expressed the intent to "preserve[] the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary[.]" H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034. Congress specified that all decisions "of a medical nature" were for the Secretary, and law enforcement decisions, such as those relating to security and record keeping, were to be made by the U.S. Attorney General. *Id.*

In 1984, Congress again amended the CSA in the Dangerous Drug Diversion Control Act of 1984 (DCA). Pub. L. No. 98-473, 98 Stat. 2070 (1984). Among other changes, the amendments changed the manner for registering physicians and other practitioners. Under the original 1970 provisions, the U.S. Attorney General was required to register physicians if they were authorized to dispense or conduct research with controlled substances in the state in which they practiced. The DCA amended that provision, adding a "public interest" consideration, which was similar to the existing

registration provisions for manufacturers and distributors. *See* 21 U.S.C. §§ 823(a), (b), (d), (e). The DCA specified five factors to be considered in determining the "public interest," including compliance with state law and threats to public health and safety. 21 U.S.C. § 823(f); H.R. Rep. 98-835, Part I, at 14 (1984). Additionally, the DCA amended the revocation and suspension provisions of the CSA, 21 U.S.C. § 824(a), to conform to changes made to the registration provision. H.R. Rep. 98-835, Part I, at 14.

2. When some members of Congress complained to then-Attorney General Janet Reno that the DWDA authorized a use of controlled substances that violated the CSA, she disagreed. After a "thorough and careful review" by the Justice Department, Attorney General Reno concluded that the CSA was intended "to prevent both the trafficking in [controlled] substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress sought to prevent was that deriving from the drug's 'stimulant, depressive, or hallucinogenic effect on the central nervous system.' 21 U.S.C. § 811(f)." Or. Br. in Opp. Supp. App. 3-4. Attorney General Reno could find no evidence that, "in the CSA, Congress intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." *Id.* at 4. She noted that the CSA was "essentially silent" about "regulating the practice of medicine that involves legally available drugs," with one exception dealing with treating addicts. "Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign the [Drug Enforcement Administration] the novel role of resolving the 'earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide,' *Washington v. Glucksberg*, [521 U.S. 702, 735] (1997),

simply because that procedure involves the use of controlled substances." *Ibid.* Determining whether conduct permitted by the DWDA "falls outside the legitimate practice of medicine and is inconsistent with the public interest" are "fundamental questions of morality and public policy" that are "well beyond the purposes of the CSA." *Ibid.*

But as the court of appeals noted, "[w]ith a change of administrations came a change of perspectives." App. to Pet. for Cert. 8a. In 2001, then-Attorney General John Ashcroft sought an opinion from the Office of Legal Counsel (OLC) in the U.S. Department of Justice about whether a prescription issued under the DWDA is a valid prescription under the CSA and its implementing regulations. The opinion concluded that "assisting in suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04(a) that would justify a physician's dispensing controlled substances." App. to Pet. for Cert. 114a.

Relying on the OLC opinion and a regulation providing that a prescription for a controlled substance is "effective" only if issued for a "legitimate medical purpose," 21 C.F.R. § 1306.04, then-Attorney General Ashcroft issued a directive (Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607; App. to Pet. for Cert. 100a-05a) (directive), in which he concluded that physicians who prescribe controlled substances to assist a patient to hasten his or her own impending death violate the CSA, making them subject to sanctions including criminal prosecution and loss of their ability to prescribe controlled substances.

The directive made clear that those conclusions applied regardless of whether state law authorized or permitted such use. App. to Pet. for Cert. 102a. The directive also instructed the Drug Enforcement Administration (DEA) to look to the required medical documentation and reporting requirements under the DWDA, which "should contain the information

necessary to determine whether those holding DEA registrations who assist suicides in accordance with Oregon law are prescribing federally controlled substances for that purpose in violation of the CSA as construed by this Memorandum and the attached OLC Opinion." *Id.* at 104a.

3. Seeking to protect its physicians, its ability to regulate the practice of medicine, and its sovereign ability to implement the will of Oregon's people by providing competent terminally ill adults with a right Oregonians twice voted to confer, Oregon brought suit in the United States District Court for the District of Oregon. The State asserted, in part, that the directive exceeded the U.S. Attorney General's authority because Congress did not authorize the U.S. Attorney General to override the States' right to regulate the practice of medicine. A doctor, a pharmacist, and several terminally ill Oregonians intervened.

The District Court agreed that nothing in the CSA supports the U.S. Attorney General's conclusion that Congress intended to substitute his judgment for the historic authority of the State to determine the scope of legitimate medical practice. Consequently, the court permanently enjoined enforcement of the directive.

The District Court began with this Court's opinion in *Washington v. Glucksberg*, 521 U.S. 702 (1997), which, the court noted, acknowledged the "earnest and profound debate" about end-of-life treatment occurring in the States. App. to Pet. for Cert. 66a-67a. Although the District Court agreed that the CSA gives the U.S. Attorney General and the DEA "broad authority to regulate controlled substances," the court concluded: "No provision of the CSA, however, alone (as defendants urge) or viewed as a 'symmetrical and coherent scheme' demonstrates or even suggests that Congress intended to delegate to the Attorney General or the DEA the authority to decide, as a matter of national policy, a question

of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice." App. to Pet. for Cert. 87a.

Nor could the court find support for the U.S. Attorney General's position in the legislative history of the CSA. Rather, that history overwhelmingly supported the conclusion "that Congress' intent was to address problems of drug abuse, drug trafficking, and diversion of drugs from legitimate channels to illegitimate channels." *Id.* at 89a-90a. Finally, the court noted that none of the cases on which the U.S. Attorney General relied involved doctors or pharmacists who were acting in compliance with state law. *Id.* at 92a-93a (citing, *inter alia*, *United States v. Moore*, 423 U.S. 122 (1975)). In concluding, the court stated: "The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. . . .The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board." App. to Pet. for Cert. 94a-95a.

Petitioners appealed, and the court of appeals affirmed. That court, too, began its analysis with *Glucksberg*. App. to Pet. for Cert. 9a. The court noted this Court's statement that determining whether to permit physicians to aid those who wished to hasten death "belongs among state lawmakers," *ibid.* (citing 521 U.S. at 735), in the "'laboratory' of the States." *Ibid.* (quoting 521 U.S. at 737 (O'Connor, J., concurring)). As the District Court had, the court of appeals explained that States bear, and historically have borne, primary responsibility for regulating medical care. App. to Pet. for Cert. 10a. Therefore, unless the federal statute in question is "unmistakably clear," the courts will not conclude that Congress intended to alter that federal balance. *Id.* at 11a. And as the District Court did, the appeals court concluded that "Congress has provided no indication—much less an

'unmistakably clear' indication—that it intended to authorize the Attorney General to regulate" the practice of medicine in this context. *Id.* at 12a. The court of appeals' review of the legislative history confirmed that Congress was concerned with drug abuse, drug addiction, and the diversion of controlled substances out of legitimate channels, not with substituting the U.S. Attorney General's judgment for that of state regulators. *Id.* at 18a-20a. Because Congress had not expressed its clear intention to replace the States as the regulators of medical practice, the court concluded that it was "under no obligation to defer to the Attorney General's interpretation of his role under the statute and its implementing regulations." *Id.* at 21a.

The dissenting opinion concluded that the U.S. Attorney General's interpretation of the "legitimate medical purpose" regulation was valid and controlling. Generally rejecting the majority's analysis, the dissent determined that the CSA was not limited to combating drug abuse, App. to Pet. for Cert. 34a-36a; that Congress did not intend to preserve the States' traditional authority over the practice of medicine if that practice involved controlled substances, *id.* at 36a; and that the "clear statement" rule does not apply to the CSA, *id.* at 45a-47a. Ultimately, the dissent concluded that the directive was an interpretation of the agency's "legitimate medical purpose" regulation, not an interpretation of the CSA itself, *id.* at 54a, and it was therefore entitled to be judged under a "highly deferential standard of review," *id.* at 55a. Applying that standard, the dissent found the directive to be lawful and binding. *Id.* at 56a.

Summary of Argument

Congress enacted the CSA to prevent diversion of drugs out of legal channels and into illegal markets. As one means to that end, the Act divides controlled substances into those that have no accepted medical uses and those that do. Here,

petitioners have singled out a particular medical practice, one affirmatively authorized and regulated by state law, and insisted that no controlled substance, even those having accepted medical uses, may be used for that purpose even in the absence of evidence of diversion. That the U.S. Attorney General's action here is apparently unprecedented does not, by itself, mean that the CSA does not authorize the power petitioners claim. Nevertheless, petitioners can point to no explicit language in the CSA authorizing the U.S. Attorney General to outlaw particular medical practices involving drugs that admittedly have accepted medical uses. Indeed, nothing in the text or history of the CSA suggests that Congress intended to authorize a federal agent to override the States' historic power to regulate medical practice. As then-Attorney General Reno explained, the Act is "essentially silent" about "regulating the practice of medicine that involves legally available drugs." Or. Br. in Opp. Supp. App. 4. Petitioners must, therefore, rely on inherently ambiguous terms, such as "legitimate medical purpose" to support their claim of authority.

That failure to find explicit authority should be dispositive. This Court repeatedly has explained that the historic role of the States in the federal system demands special consideration. Where the traditional police powers of the States, such as regulating the practice of medicine, are at stake, the Court will find that Congress intended to displace the States only where the statute in question makes that intention unmistakable. Where that clear statement requirement applies, it is a condition precedent to the deference under *Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), that the U.S. Attorney General claims.

The Court applies a similar and related rule of statutory construction when congressional action would push the limits of constitutional authority. While Congress may expressly

determine that particular drugs have no accepted uses, as it did with marijuana, Congress has neither made that determination about the drugs at issue here nor expressed the intention to transfer the regulation of medical practice from the States to the U.S. Attorney General. What the U.S. Attorney General seeks to regulate in this case is neither the commercial aspect of the interaction between doctor and patient, nor the amount of the drug that is prescribed; it is, rather, the intention of the parties to that transaction. While intent is significant in many contexts, the Court would have to break new constitutional ground to determine that the Commerce Clause power extends to regulating the doctor-patient relationship at that level.

Petitioners argue, incorrectly, that the clear statement requirement does not apply here, but they do not suggest that, if it does, the CSA contains such a statement. Because the language of the CSA does not demonstrate clearly that Congress intended to displace the States as the traditional regulators of medical practice or that it intended to authorize the U.S. Attorney General to push Congress's constitutional authority to the extent that would be required to sustain the claim made here, the Court's prudential rules require rejection of petitioners' argument.

ARGUMENT

This Court has acknowledged the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide" ongoing throughout the nation. *Glucksberg*, 521 U.S. at 735; *id.* at 737 (O'Connor, J., concurring) (same); *id.* at 738 (Stevens, J., concurring in the judgments) (same); *id.* at 753 (Souter, J., concurring in the judgment) (noting lack of unanimity about the practice, accepting representation that providing drugs to hasten death would be consistent with standards of medical practice in appropriate circumstances). *Glucksberg* also acknowledged

the gradual evolution of attitudes about physicians assisting dying people to end their lives, especially in light of modern reexamination of end-of-life care. *Id.* at 710-19. "Public concern and democratic action are therefore sharply focused on how best to protect dignity and independence at the end of life, with the result that there have been many significant changes in state laws and in the attitudes these laws reflect." *Id.* at 716.[4]

While *Glucksberg* was still in the courts, the people of Oregon took the controversial step that led to this litigation. Subject to the stringent limitations already described, they granted themselves the right to enlist the aid of physicians if they choose to end their own life rather than suffer the pain or the loss of control and dignity that often accompanies terminal illness.[5] Between 1998, when the DWDA was implemented, and 2004, the latest complete reporting period, 208 persons in Oregon died after ingesting a lethal dose of Schedule II controlled substances prescribed pursuant to that statute. Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act*, 20 (2005) (Seventh Annual Report).

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[4] The opinions in *Glucksberg* belie petitioners' claim that the medical practice authorized by the DWDA is subject to universal condemnation. *See* Pet. Br. 21-24. Oregon's disagreement with that claim is explicit in the DWDA itself. The brief of the patient intervenors describes the disagreement of others.

[5] In 2004, 87% of those who requested lethal prescriptions reported that they did so, at least in part, because they feared loss of control; 78% loss of dignity. Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act*, 15 (2005). The report can be found at http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf.

After congressional efforts to derail Oregon's experiment failed, the U.S. Attorney General issued his directive. The directive asserted that prescribing controlled substances for the purposes authorized by the DWDA would render a physician liable to lose the ability to prescribe controlled substances, *id.* at 102a, and asserted further that the DEA could and should obtain state records identifying those physicians who were implementing the Oregon law. *Id.* at 103a-104a. The OLC memorandum also noted the possibility of criminal prosecution. *Id.* at 112a. The threat was patent: physicians who prescribed controlled substances for the purposes authorized by the DWDA risked their ability to prescribe medication for their patients, which is equivalent to risking their professional lives, and they risked their freedom.

But as former Attorney General Reno, the District Court, and the court of appeals all concluded, the CSA contains scant support for the U.S. Attorney General's claim of authority to take those steps. "The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Raich*, 125 S. Ct. at 2203 (footnotes omitted). "To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Id.*

Although Congress designed the CSA primarily to prevent diversion of drugs into illicit markets, neither the OLC analysis nor the U.S. Attorney General's directive suggested that drugs prescribed under the DWDA had been diverted into illicit markets, that the DWDA created a realistic possibility of diversion, or that, even if it did, the amounts in question could have any noticeable impact on the war on drugs. App.

to Pet. for Cert. 100a-148a. Nor does petitioners' brief address diversion.[6] In sum, neither diversion nor abuse of controlled substances, as those terms are defined in the CSA, is at issue in this case and petitioners are required to break new ground under the CSA by claiming authority not previously exercised by the U.S. Attorney General and not previously recognized by the courts.

While it is now settled that Congress can determine that certain drugs have no accepted medical uses and may punish their possession, *Raich*, the drugs at issue here are not the Schedule I drugs about which Congress has made that determination. They are, rather, Schedule II drugs, which do have accepted uses. Notwithstanding that the language and history of the CSA reveal no intent to displace state regulation of the reasons for which doctors may prescribe those admittedly useful drugs, the U.S. Attorney General claims that Congress mandated a uniform national standard for the prescriptions doctors may write for them, or at least empowered him to make a use-by-use, nationally binding

[6] Petitioners do repeat their conclusory assertion that taking drugs for the purposes authorized by the DWDA "*is* a form of 'drug abuse.'" Pet. Br. 45 (emphasis in original). But the particular drug abuse, as defined in the CSA, that Congress intended to prevent was that deriving from the drug's "stimulant, depressant or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f). Although the drugs used under the DWDA are chosen for their "depressant . . . effect on the central nervous system," that is equally true of every prescription for those drugs, which are primarily used as sedatives and sleep aids. U.S. National Library of Medicine and National Institutes of Health, *Medline Plus*, http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202081.html (June 27, 2005).

determination of which prescriptions are legitimate. *See* Pet. Br. 29 (asserting that his decision about which particular uses are legitimate should be binding on the States).

To support their groundbreaking claims, petitioners assert that the CSA prohibits all uses of controlled substances that it does not authorize and authorizes doctors to prescribe those substances only for "legitimate medical purposes." Oregon could hardly disagree; that is what the Act states. But the issue in this case turns on whether, in the absence of diversion or abuse as those terms are defined in the CSA and without following any procedure specified in that Act, the U.S. Attorney General may simply overrule a State's determination about the validity or legitimacy of a medical practice. Petitioners are forced to base their claim of authority to take that step primarily on what Congress did not say. They reason that "[b]ecause nothing in the CSA . . . makes the definition of 'legitimate medical purpose' or 'treatment' depend upon state law, this Court's decisions in *Mississippi Band* [*of Choctaw Indians v. Holyfield*, 490 U.S. 30 (1989)] and similar cases mandate that those phrases be given uniform federal definitions and not vary from State to State." Pet. Br. 25.[7]

[7] In light of the central differences between the parties about the issues in this case, petitioners' reliance on *Mississippi Band* borders on ironic. There, the Court had no trouble discerning that the text of the statute at issue, its legislative history, and the hearings leading to its enactment all clearly demonstrated Congress's intent to displace state court jurisdiction over Indian children. 490 U.S. at 43-45. The Court's determination that Congress intended a uniform national definition of domicile flowed from that determination of manifest congressional intent, not from ambiguity or silence.

Petitioners' claim is wrong in the first instance because the CSA does not demonstrate the intent to create the national standard on which they rely. Rather, Congress demonstrated its intent to respect state laws governing medical practices and disclaimed the intent to displace state law—including the intent to permit the U.S. Attorney General to displace state law—except in the event of direct conflict between the CSA itself and state law, a conflict that is absent here.

Moreover, rules of statutory construction lead to a different conclusion than the one petitioners draw. Petitioners claim that because Congress did not make itself clear about the meaning of terms such as "legitimate medical purpose," the Court must either infer that a uniform federal standard was intended under *Mississippi Band* or defer to the U.S. Attorney General under *Chevron*. But this Court has refused to infer congressional intent to displace the States' historic police power from congressional silence or ambiguity, especially where doing so would push the limits of Congress's constitutional authority. *E.g.*, *Solid Waste Agency of Northern Cook Cty. v. Army Corps of Engineers*, 531 U.S. 159, 172-74 (2001). Rather, where historic state powers like the power to regulate medical practice are implicated, only a clear statement of congressional intent to displace those historic powers is sufficient. *Ibid.* And where, as here, a clear statement of congressional intent is required, that clear statement is a condition precedent for a successful claim to deference. *Ibid.*

I. The U.S. Attorney General's threatened action would nullify the DWDA.

Petitioners argue that the U.S. Attorney General's threatened action "[a]t most," would "frustrate the purposes" of the DWDA. Pet. Br. 43-44. That claim is asserted primarily in an effort to persuade the Court that principles applied when federal law preempts state law have no role in this case. *Ibid.*

But petitioners fail to acknowledge that the U.S. Attorney General's threatened actions would make the DWDA completely ineffective, and their reasons for not applying the presumption against preempting state law in this area of traditional state regulation are peculiarly unpersuasive.

A. The DWDA does not merely "decriminalize physician assisted suicide."

Petitioners attempt to diminish the DWDA by describing it as merely "decriminalizing assisted suicide." Pet. Br. 13. That characterization says both too much and too little. It says too much because aiding another to commit suicide remains a crime in Oregon under most circumstances. Or. Rev. Stat. § 163.125(1)(b). And even those physicians who provide a prescription to enable a person to end his or her own life and those pharmacists who fill that prescription may not give any physical assistance to the patient if the patient chooses to take the drugs. More importantly, petitioners' description says too little because it fails to acknowledge that the people of Oregon have made an affirmative policy choice to grant themselves and their loved ones the right to avoid the intractable pain or the loss of control and dignity that accompany some forms of fatal disease. In making that choice, Oregon has not merely taken hands off. It has, rather, enacted a comprehensive set of regulations intended to ensure that only terminally ill persons with less than six months' expected lifespan who are capable of making a competent and informed choice may receive drugs, with the concurrence of at least two physicians, to hasten death. In short, the DWDA does not merely "decriminalize assisting suicide," it regulates and limits that practice.

Petitioners also claim that physicians could use other methods of aiding patients to hasten death. Pet. Br. 44. In rejecting that same argument, the court of appeals found it clear that controlled substances are "the best and most reliable

means for terminally ill patients to painlessly take their own lives." App. to Pet. for Cert. 8a n. 5. Participating Oregon doctors unanimously agree; all doctors who have aided patients under the DWDA have prescribed Schedule II controlled substances. Seventh Annual Report, at 14. Even if some other method or drug might work, preventing Oregon physicians from using the most effective and humane means of easing death, the means chosen in every case by every physician, would make the law largely ineffective by making the ability to provide a quick, sure, and painless death speculative at best.

As the court of appeals also noted, the provision of the CSA on which the U.S. Attorney General relies for his claim of authority is not limited by its terms to conduct involving controlled substances. App. to Pet. for Cert. 8a n. 5. That section permits the U.S. Attorney General to deregister physicians whose conduct is "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). The terms of that section do not require that the conduct leading to deregistration be connected with controlled substances. If the U.S. Attorney General can deregister a physician who prescribes controlled substances in the manner permitted by the DWDA in the absence of any evidence of diversion because he concludes that doing so is "inconsistent with the public interest," he can deregister any physician who provides similar medical aid to a terminally ill patient, notwithstanding that the aid does not involve the use of controlled substances. In light of the obvious reality that no physician can afford to risk the ability to prescribe medicine for his or her patients, the breadth of power petitioners claim is nothing less than the power to prevent the operation of the DWDA in its entirety.

B. The principles underlying the presumption against preemption apply here.

Petitioners assert that the U.S. Attorney General's directive would not "invalidate" the DWDA. Pet. Br. 43; *citing California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280 (1987)). And they stress that the DWDA retains its "undeniable effects on state law." Pet. Br. 44. But they draw the wrong conclusion—that the presumption against preemption is inapposite, Pet. Br. 43—from those assertions. First, although petitioners are correct that the DWDA would continue to shield physicians from state prosecution, that shield would be meaningless if no physician would dare risk federal prosecution or deregistration. More significantly, enactment of federal criminal laws does not "invalidate" state criminal laws aimed at the same conduct, in that that conduct may still be prosecuted in the state courts. Nevertheless, this Court applies the same clear statement requirement when determining whether federal criminal laws apply to crimes traditionally prosecuted by the States. "'[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance' in the prosecution of crimes." *Jones v. United States*, 529 U.S. 848, 858 (2000) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)). *See id.* at 859-60 (Stevens, J., concurring) (noting the "kinship" between the presumption against preemption, the Court's reluctance to believe that Congress intended to intervene in criminal law, a matter of traditional state governance, and the clear statement requirement).

Consequently, even if it were technically accurate to describe what the U.S. Attorney General seeks to do here as something other than "preemption," it is difficult to see why different principles would govern total frustration of state laws. *Department of Revenue of Ore.* v. *ACF Industries, Inc.*, 510 U.S. 332, 345 (1994) (applying presumption against

preemption when "determining the breadth of a federal statute that *impinges upon or* pre-empts the States' traditional powers"; *citing Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 533 (1992) (emphasis added). The U.S. Attorney General's threats will prevent state law from operating as state lawmakers intended. The affront to the State's sovereignty is the same in kind, even if not necessarily in degree, as it would be if he were able simply to declare the DWDA invalid.

II. The CSA does not itself prohibit the uses of controlled substances permitted by the DWDA, and it does not authorize the U.S. Attorney General to do so.

A. Neither the text of the CSA nor judicial interpretations of that text suggest that Congress intended to displace the States' traditional power to regulate medical practice, even when controlled substances are involved.

1. The text generally and judicial interpretations

Petitioners contend that the text of the CSA demonstrates that Congress itself prohibited use of controlled substances for the purposes specified in the DWDA or, at a minimum, delegated to the U.S. Attorney General the authority to prohibit those uses. They argue that this conclusion follows from the CSA's prohibition on prescribing controlled substances except for a "legitimate medical purpose" and in the "usual course of professional treatment," a prohibition they describe as "central" to the "comprehensive national scheme Congress established to regulate controlled substances." Pet. Br. at 14.

What is "central" to the CSA is the "closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§ 841(a)(1),

844(a)." *Raich*, 125 S. Ct. at 2203. *Moore* explains that Congress intended that closed system to prevent diversion of controlled substances outside of "the legitimate distribution chain." 423 U.S. at 141. Whether conduct violated the CSA "was intended to turn on whether the 'transaction' falls within or without legitimate channels." *Id.* at 135. The federal registration system "contemplates that [the physician] is authorized by the state to practice medicine and to dispense drugs in connection with his professional practice." *Id.* at 141. This Court agreed that the CSA authorized Dr. Moore's conviction in large measure because the evidence was sufficient to demonstrate that he "acted as a large-scale 'pusher' – not as a physician." *Id.* at 143.[8]

Consistent with *Moore*, lower federal courts have enforced the CSA by assessing whether the transaction at issue in a particular case amounts to diversion outside legitimate channels of distribution. The Fifth Circuit, for example was "able to glean from reported cases" nine factors that would support a finding that the physician had engaged in transactions that were prohibited by the CSA. *United States v. Rosen*, 582 F.2d 1032, 1035-36 (5th Cir. 1978) (identifying factors tending to show that physicians were acting as "pushers," such as prescribing inordinately large amounts of controlled substances and issuing large numbers of prescriptions for them). Other courts of appeal have followed a similar approach. *E.g.*, *Humphreys v. Drug Enforcement Admin.*, 96 F.3d 658, 666 (3rd Cir. 1996) (vacating DEA's decision to revoke a physician's registration because the

[8] The Court noted that the jury made that finding after being instructed that Dr. Moore could not be convicted if he merely made an honest effort to dispense drugs "in compliance with an accepted standard of medical practice." *Id.* at 142 n. 20.

evidence proffered by DEA showed that "the potential for diversion is so unlikely as to be unsustainable"); *United States v. Rosenberg*, 515 F.2d 190, 197, 199 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975) (affirming doctor's conviction where the jury was instructed that doctor violated the CSA if he "was not acting in good faith as a doctor, but simply pushing pills"). The issue consistently has been whether the defendant was acting as a "pusher"—dispensing drugs outside the CSA's "closed system"—rather than acting as a physician. Juries typically make that determination based on the circumstances of each case. "In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options. *Doe v. Bolton*, 410 U.S. 179 (1973). Hence, '[w]hat constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances.' *Linder v. United States*, [268 U.S. 5, 18 (1925)]." *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973).

Oregon has found no previous instance in which the U.S. Attorney General interpreted the CSA to authorize prosecution or deregistration of physicians for conduct having no nexus to diversion.[9] Nor has it found evidence that, before this case, anyone interpreted these provisions to authorize the

[9] To their credit, petitioners do not claim that prescribing drugs for the purposes authorized by the DWDA creates any greater risk of diversion of drugs than would occur with any other prescription for those same drugs. Indeed, petitioners have not shown that any illicit market for those drugs exists. *See* OLC Memo, App. to Pet. for Cert. 106a-148a. That memo strongly suggests what should be apparent in any event: the U.S. Attorney General's action here has always been focused on Oregon's policy choice, not on the controlled substances used to implement that choice.

U.S. Attorney General to single out a particular medical practice and determine that no controlled substances may be used for that practice.

That former restraint was consistent with the limited authority the CSA grants the U.S. Attorney General. Textual references to "legitimate medical purpose" and the "usual course of professional practice" reveal that Congress intended to delegate limited factfinding—not broad policymaking—authority to the U.S. Attorney General in respect to the scheduling and use of controlled substances. The U.S. Attorney General's scheduling authority, for example, gives him authority to list a substance on a CSA schedule only if he "finds" that it has a potential for abuse and "makes . . . the findings" specified in the CSA. 21 U.S.C. § 811(a)(1)(A) and (B). Although petitioners claim that the U.S. Attorney General could simply move the drugs used under the DWDA to Schedule I, then move them back to Schedule II with restrictions, Pet. Br. 30, that overstates his authority. Except when making temporary changes, *see Touby*, 500 U.S. at 163, the U.S. Attorney General must obtain the Secretary's agreement to schedule any previously unscheduled drugs or to change the schedule in which a drug has been placed. 21 U.S.C. § 811(a) and (b).[10] "This explicit delegation of

[10] Pointing to a Medicare manual, Pet. Br. 47 n. 18, petitioners assert that there is "no conflict" between the U.S. Attorney General's views and those of the Secretary. Assuming that manual has any application to the question before the Court, the process specified in the CSA requires more than an absence of conflict; it requires the Secretary to make a medical and scientific evaluation and it requires the U.S. Attorney General to engage in specifically defined hearings to allow comment on the medical and scientific evidence. None of that happened here.

authority to *apply* prescribed statutory criteria is not equivalent to an explicit delegation of authority to *define* those criteria." *Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881, 885 n. 5 (1st Cir. 1987) (emphasis in original).

Thus, when petitioners assert that the U.S. Attorney General's authority to determine whether "a *particular* use" of a controlled substance is permissible should be no less binding than his decision that a substance has no accepted medical use, Pet. Br. 29 (emphasis in original), they understate the authority they claim. To schedule or reschedule a drug, the U.S. Attorney General must obtain the Secretary's approval and follow specified procedures. Because he did none of those things here, petitioners necessarily are claiming that the U.S. Attorney General may identify particular medical practices to which no otherwise approved controlled substances may be put, and that he may do so without obtaining medical and scientific approval from the Secretary, without notice or hearing, and without following any congressionally specified process.[11]

[11] Some Schedule II drugs have "a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B). That suggests that the U.S. Attorney General, following specified procedures and with the concurrence of the Secretary, could impose limits on individual drugs. To accomplish the goal identified in the directive, however, he would have to take that step for each and every controlled substance or, at least, all that are capable of causing a swift, sure, and painless death. The CSA contains no textual or historic support for the proposition that Congress intended to authorize anything of that sort. And in any event, that is not what he attempted here. Rather, he has focused on a specific medical practice and determined that no controlled substance may be used for that purpose, something about which the

2. The "anti-preemption clause"

The text of the CSA shows that Congress did not intend to grant the U.S. Attorney General the regulatory authority claimed here. In every preemption case, the purpose of Congress is "the ultimate touchstone." *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Here, the text contains a clear expression of Congress's intention not to displace any more state law than absolutely necessary. 21 U.S.C. § 903 provides:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

When Congress has intended to authorize agencies to enact rules or regulations that would preempt state law, it has said so expressly. *E.g.*, 7 U.S.C. § 2156(h).[12] That Congress knows

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CSA is simply silent. And, of course, he followed no specified procedures and did not obtain the agreement of the Secretary.

[12] That section provides:

> The provisions of this chapter shall not supersede or otherwise invalidate any such State, local, or municipal legislation or ordinance relating to animal fighting ventures

how to authorize agencies to preempt state law and did not do that here demonstrates that Congress intended to supersede only state laws that conflict with the terms of the CSA itself, not with regulatory interpretations. *See, e.g., Argentine Republic v. Amerada Hess Shipping*, 488 U.S. 428, 440 (1989) (when it wants to, Congress knows how to include the high seas within statute's jurisdictional reach, citing examples; failure to do so invokes the canon of construction that legislation applies only within territorial United States); *NLRB v. Action Automotive, Inc.*, 469 U.S. 490, 497 (1985) (similar). It follows, therefore, that petitioners should not be able to rely on the U.S. Attorney General's regulations to support their claim. Rather, they should have to demonstrate a positive conflict between the DWDA and the text of the CSA itself.

B. The CSA contains no clear statement of intent to displace state regulation of medicine.

In rejecting petitioners' arguments, the court of appeals relied heavily on the absence of a clear statement of congressional intent to displace the States as the regulators of medical practices. App. to Pet. for Cert. 11a-13a. The requirement of a clear statement serves separate goals depending on whether it is invoked to protect historic state powers or to implement the Court's prudential reluctance to

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> except in case of a direct and irreconcilable conflict between any requirements thereunder and this chapter *or any rule, regulation, or standard hereunder*.

(Emphasis added). Other anti-preemption provisions similarly refer to conflicts with the statute or with rules, regulations, or orders enacted to carry out the statute's purposes. *E.g.*, 15 U.S.C. § 78bb(a); 30 U.S.C. § 955(a).

reach constitutional issues needlessly. Where one construction of a statute would impinge upon traditional state regulatory powers, the Court's insistence on finding unmistakable evidence of Congress's intent protects state sovereignty; and where one construction would call upon the Court to decide difficult and sensitive constitutional questions, a clear statement ensures that the Court is not forced to decide them unnecessarily. *Solid Waste Agency*, 531 U.S. at 172-74.

Particularly where, as here, the constitutional question implicates the Commerce Clause, those goals may overlap or even converge. In some cases, the States must depend upon their representatives in Congress to protect their prerogatives when Congress exercises its commerce powers. *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985). For that reason, the Court is careful to ensure that the political process on which the States must rely has been given an opportunity to work. That can happen only if the text of a proposed law clearly informs members of Congress that their vote could impinge upon the existing powers or rights of the States themselves or of individual constituents. Consequently, the Court must be "absolutely certain that Congress intended" that result. *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991). "'[T]o give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Id.* (quoting L. Tribe, *American Constitutional Law* § 6-25, p 480 (2d ed. 1988) (brackets by the Court; emphasis in original)).

Similar reasons support the clear statement rule when congressional action would intrude upon "the historic powers of the States, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)....'In traditionally sensitive areas, such as legislation affecting the federal balance, the requirement of [a] clear statement assures that the legislature has in fact

faced, and intended to bring into issue, the critical matters involved in the judicial decision.'" *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989) (quoting *Bass*, 404 U.S. at 349). The presumption against preemption of State laws "provides assurance that the federal-state balance will not be disturbed unintentionally by Congress, or unnecessarily by the courts." *Gade v. National Solid Wastes Management Ass'n.*, 505 U.S. 88, 116 (1992) (Souter, J., dissenting) (citation and internal quotation marks omitted). Consequently, whether the issue is the historic powers of the States or the extent of Congress's commerce power, the clear statement rule ensures that the States' prerogatives are not displaced by accident or inadvertence.

That caution on the Court's part serves, among other things, to maintain the division of powers between the state and federal governments embodied in the federal structure. That division was, of course, an essential part of the founders' design, and one of our nation's "first principles." *United States v. Lopez*, 514 U.S. 549, 552 (1995). "'The powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain with the States are numerous and indefinite.'" *Ibid.* (quoting The Federalist No. 45, pp. 292-293 (James Madison) (C. Rossiter ed. 1961)).

But the benefits of federalism are not merely quaint relics of simpler days, trotted out from time to time to placate parochial interests. This Court has recently and repeatedly reaffirmed the importance of the state-federal balance as a bulwark against the excessive aggregation of power in either state or federal government. "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of

tyranny and abuse from either front." *Gregory*, 501 U.S. at 458. Thus, the "constitutionally mandated division of authority was adopted by the Framers to ensure protection of our fundamental liberties." *Lopez*, 514 U.S. at 552 (citation and internal quotation marks omitted). The clear statement rule helps defend that division of authority and is "an acknowledgement that the States retain substantial powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory*, 501 U.S. at 461.

Petitioners take a parsimonious view of both the Court's insistence on protecting state sovereignty and the clear statement rule implementing that protection. They claim that the U.S. Attorney General's interpretation is entitled to *Chevron* deference. They assert that the clear statement rule is narrowly limited, applying only to federal statutes that implicate the heart of state sovereignty. Pet. Br. 38. And they argue that giving any consideration to state law would turn the Supremacy Clause "on its head." *Id.* at 44 and n. 17.

1. Because the U.S. Attorney General's action here would displace traditional state authority, a clear statement is a condition precedent to that action or to *Chevron* deference.

This Court will not impute to Congress the intent to alter the usual state-federal balance or push the limits of congressional power unless the text of the statute in question makes that intent unmistakable. *Solid Waste Agency*, 531 U.S. at 172-74; *Jones*, 529 U.S. at 858-59. Administrative authority to displace state authority in areas historically regulated by the States must likewise be supported by clear statutory language. *Solid Waste Agency*, 531 U.S. at 172 (citing *Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988)); *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 715-16 (1985); *see also FDA v. Brown &*

Williamson Tobacco Corp., 529 U.S. 120, 125 (2000) ("Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'") (quoting *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988)).[13] Consequently, the U.S. Attorney General's claim to deference in applying the CSA here must surmount the "clear statement" hurdle because it impinges upon the DWDA at the margins of Congress's powers under the Commerce Clause.

2. The clear statement rule applies more broadly than petitioners acknowledge.

Petitioners' discussion of the clear statement rule focuses almost exclusively on *Gregory*, on which the court of appeals relied. Petitioners chide the lower court for that reliance, asserting that *Gregory* applies only where federal law "would encroach upon how a State defines itself as a Sovereign." Pet. Br. 38 (internal quotation marks omitted).

Gregory itself suggests that the rule it applied extends beyond the structural-sovereignty limits petitioners seek to

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[13] *Chevron* has been described as establishing a "two-step procedure for evaluating whether an agency's interpretation of a statute is lawful." *National Cable & Telecommunications Assn. v. Brand X Internet Services*, 545 U.S. ___, ___ (June 27, 2005) (slip op. at 14); *accord Brown & Williamson Tobacco Corp.*, 529 U.S. at 132. Some commentators call the preliminary step—determining whether a clear statement is needed in particular cases—"step zero." Cass R. Sunstein, *Chevron Step Zero*, 92 Va. L. Rev. (forthcoming April 2006) (available at http://ssrn.com/abstract=739129; last visited June 29, 2005); Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 Geo. L. J. 833, 873 (2001).

impose. In discussing the "delicate balance" of federalism, the Court recognized that the Supremacy Clause allows Congress to legislate in "areas" traditionally regulated by the States, "a power that we must assume Congress does not exercise lightly." 501 U.S. at 460. To be sure, the Court noted that the issue in *Gregory* itself went "beyond an area traditionally regulated by the States" to touch upon matters "of the most fundamental sort for a sovereign entity." *Id.* While those fundamental matters unquestionably added weight to the state interest involved, the Court did not suggest that *only* matters "fundamental" to a State's identity as a sovereign are sufficient to invoke the respect to which State sovereignty is entitled or the clear statement rule that serves to protect that interest. To the contrary, in endorsing and applying the clear statement rule, *Gregory* cited *Bass*, which addresses the States' traditional authority over criminal law, and *Rice*, which dealt with regulation of grain storage elevators. 501 U.S. at 461.

And the Court subsequently has suggested a broader view of *Gregory* than petitioners acknowledge. In *Raygor v. Regents of the University of Minnesota*, 534 U.S. 533, 543-44 (2002), the Court relied on *Gregory* to support its holding that a clear statement was needed to demonstrate congressional intent to extend the statute of limitations for a federal claim against a State in the State's courts. Even if extending the statute of limitations did not necessarily abrogate the States' sovereign immunity, it "at least affects the federal balance in an area that has been a historic power of the States[.]" *Raygor*, 534 U.S. at 544. *See also United States v. Morrison*, 529 U.S. 598, 662-63 (2000) (Breyer, J., dissenting) (*Gregory* insists upon a "'plain statement' of legislative intent when Congress legislates 'in areas traditionally regulated by the States.'"); *Lopez*, 514 U.S. at 611 (Souter, J., dissenting) (clear statement rule applies "in cases implicating Congress's

historical reluctance to trench on state legislative prerogatives or to enter into spheres already occupied by the States," citing *Gregory*).[14]

Even if *Gregory* were as limited as petitioners contend, it is neither the first nor the only case to establish that the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230. As noted above, *Rice* dealt with regulation of grain storage elevators, *id.* at 220-21, a subject obviously not central to how a State defines itself as a sovereign. Other cases apply the clear statement rule in areas equally far from the structure of sovereignty. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365 (2002) (state regulation of insurance not to be superseded by federal law "unless that was the clear and manifest intent of Congress"); *Jones*, 529 U.S. at 857 ("unless Congress conveys its purpose clearly, it will not be deemed to have changed the federal-state balance in the prosecution of crimes") (internal quotation marks and citation omitted); *California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997) (state wage-claim laws presumed not to be preempted unless contrary result was "the clear and manifest purpose of Congress"); *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 581 (1979) (state regulation of family law will not be overridden

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[14] In addition, the Court repeatedly has relied on *Gregory*'s description of the federalism principles that underlie the clear statement rule. *E.g.*, *Morrison*, 529 U.S. at 616 n. 7; *Lopez*, 514 U.S. at 552; *id.* at 576 (Kennedy, J., concurring); *id.* at 584 (Thomas, J., concurring); *New York v. United States*, 505 U.S. 144, 163, 182-83 (1992).

unless that result is "positively required by direct enactment").[15]

Thus, while *Gregory* may describe the clear statement rule most plainly and explain the historic and constitutional reasons for its existence and application most vividly, that case is far from standing alone in demanding application of the rule where traditional state powers—not only matters going to the heart of state sovereignty—are at stake. Consequently, petitioners' assertions that the court of appeals drastically extended the clear statement rule and that there is "no basis in this Court's precedents" for its application to this case, Pet. Br. 37, run counter to well-settled principles.

3. The CSA reflects Congress's intent to respect the States' traditional role in regulating medical practice.

Petitioners argue that Congress intended the CSA to apply uniformly nationwide and that any consideration of state law would upset that congressional design and be contrary to the presumption of uniform nationwide application. *See* Pet. Br.

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[15] Noting the breadth of the States' traditional powers, petitioners caution that application of the clear statement rule here "would mean that virtually every federal regulation would need a clear statement from Congress." Pet. Br. 39. First, of course, clarity is not generally considered a bad thing in legislative enactments. But whatever might be the outer limits of the sphere of state functions that call for a clear Congressional statement, as described in the text, pp. 38-41, the Court's cases already demonstrate that the States' regulation of the health, welfare, and comfort of their citizens falls at or near its core. Thus, the Court need neither break new ground nor define the boundaries of the clear statement rule to recognize that it applies here.

25 (citing *Mississippi Band*). To be sure, the CSA reflects a congressional conclusion that controlled substances are a matter of national concern. But that does not mean Congress intended to federalize every prescription of every controlled substance or to supplant all state laws on the subject. *Hillsborough County*, 471 U.S. at 717. "[E]very subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law." *Id.* at 719. Congress certainly can and sometimes does choose to defer to state law. *Rice*, 331 U.S. at 222-23 (explaining that Congress did as much); *Mississippi Band*, 490 U.S. at 43 ("Congress sometimes intends that a statutory term be given content by the application of state law."); *see also Geier v. American Honda Motor Co.*, 529 U.S. 861, 872 (2000) (acknowledging congressional power to mandate a "complex type of federal/state relationship" that would tolerate a conflict with ordinary preemption principles).

The text of the CSA demonstrates Congress's intent to give substantial deference to state laws. First, the disclaimer of intent to preempt state law in section 903 is plainly inconsistent with unyielding insistence on national uniformity. Second, because Congress stated that it did not intend to displace state laws "including" criminal penalties, it follows that Congress did not intend to limit the States to imposing more stringent criminal penalties. Rather, Congress necessarily intended to respect state laws that differed in other ways from the CSA.

Moreover, when Congress first enacted the CSA and when the U.S. Attorney General promulgated the "legitimate medical purpose" regulation on which he relies, 21 C.F.R. § 1306.04(a) (1971), the CSA expressly required the U.S. Attorney General to defer to state regulators and register any physician licensed by a State to dispense controlled

substances. 21 U.S.C. § 821(f) (1970). "'[R]egistration would be as a matter of right where the individual or firm is engaged in *activities* involving these drugs which are authorized or permitted under State law . . . .'" *Moore*, 423 U.S. at 141 n. 19 (quoting H.R. Rep. No. 91-1444, p. 23 (1970); emphasis and ellipses by the Court). Consequently, at the time the "legitimate medical purpose" regulation was enacted, it necessarily was true that, for purposes of determining whether a practitioner was entitled to registration, both Congress and the U.S. Attorney General intended to leave the definition of what medical purposes were "legitimate" to the States, whose laws, of course, vary.

Congress later amended the Act to permit the U.S. Attorney General to deregister a physician if he determined that registration was "inconsistent with the public interest." 21 U.S.C. § 824(a)(4) (1984). Determining whether registration is in the public interest "shall" be based on five factors, including the recommendation of State authorities. 21 U.S.C. § 823(f).[16] Indeed, of the five factors, three (nos. 1, 3, and 4)

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[16] The factors are:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
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> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
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> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

expressly require the U.S. Attorney General to consider state law, the actions of state regulators, or both. As the court of appeals explained, the 1984 amendments to this section were intended only to permit the U.S. Attorney General to act when state regulators proved ineffective in enforcing state laws. App. to Pet. for Cert. 19a-20a.[17] The court of appeals also correctly explained that Congress specifically intended the U.S. Attorney General to "continue to give deference to the opinions of the State licensing authorities." *Id.* at 20a (quoting S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449). But petitioners appear to read the "public health and safety" factor as a license to ignore the other four in favor of the "uniform

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[17] Both the House and the Senate acknowledged that the provision governing registration of state-licensed practitioners was changed because state licensing agencies were unable to ensure that all practitioners who were diverting drugs were investigated and disciplined by the states.

> [B]ecause of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants. Since State revocation of a practitioner's license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the State regulatory level have had a severe adverse impact on Federal anti-diversion efforts.

S. Rep. No. 98-225, at 266 (1984), 1984 U.S.C.C.A.N. 3182, 3448 (citation omitted); H.R. Rep. No. 98-835, Part I, at 7-8 (similar).

national standard," Pet. Br. 25, on which they insist. *Cf. ACF Industries*, 510 U.S. at 340 (a statute should be interpreted so as not to render one part inoperative). Nothing in the language or history of the Act, including the 1984 amendments, suggests that Congress ever intended to permit the U.S. Attorney General to deregister or prosecute a physician who acted in accordance with affirmative state law and in the absence of any evidence of diversion or drug abuse as that abuse is defined in the Act.

C. A clear statement is required here to support the U.S. Attorney General's threat to displace the States' traditional regulation of medical practice.

That the clear statement rule applies to protect the States' historic primacy in matters of health and medicine should be indisputable. "It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 n. 30 (1977) (citing cases). The Court not only has described the regulation of health care as within the scope of the States' traditional powers, it expressly has concluded that a clear statement is required before the Court will conclude that Congress intended to interfere with that power. *Medtronic Inc.*, 518 U.S. at 475; *Hillsborough County*, 471 U.S. at 715. In *Medtronic*, the Court relied on the States' status as "independent sovereigns in our federal system" to conclude not only that a clear statement of preemptive intent was necessary to displace state law regulating the practice of medicine, but also to support a narrow interpretation of a provision expressly preempting state law. 518 U.S. at 485. The CSA, of course, contains an unambiguous expression of intent *not* to preempt state law.

Petitioners note that Congress has regulated many aspects of health care. Pet. Br. 42-43 (citing *Medtronic*). They contend that application of the clear statement rule here

threatens uniform application of the federal laws doing so, although they may also mean to imply that Congress has enacted so many laws addressing health and health care that the States' historic power to regulate medical care has been displaced in some way or to some degree. The difficulty with either of those arguments is that the case on which they rely not only acknowledges the Federal Government's "increasingly significant role in the protection of the health of our people," *Medtronic*, 518 U.S. at 475, but also holds that the clear statement rule and the presumption against preemption apply because of "federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485.

Petitioners also argue that Oregon is not exercising its police power here. First, they contend that aid in dying is incompatible with medicine, or at least a dictionary definition of medicine, because it does not aim to restore the patient to health. *E.g.*, Pet. Br. 11, 18-20. They also contend that the DWDA cannot be within the States' traditional powers because "there *is* no tradition of State[s] authorizing physician-assisted suicide." Pet. Br. 39 (emphasis in original). But those claims take an unjustifiably crabbed view of the States' sovereignty and of their role in the federal structure.

The claim that assistance in dying is not medical treatment proves too much. Petitioners rely on dictionary definitions of medicine that include "the . . . alleviation . . . of disease." Pet. Br. 19. And they expressly exclude from the reach of the directive the palliative provision of controlled substances to alleviate pain even where the physician knows that those substances will "haste[n] the patient's death." *Id.* at 20 n. 7. Thus, the disagreement between the parties may reduce to how narrowly petitioners define "alleviation" or, more precisely, who gets to decide what degree of alleviation is within the bounds of patient care.

This Court has acknowledged that technological means of extending life, including artificial administration of food and water, are forms of medical treatment. *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 278 (1990); *id.* at 287 (O'Connor, J., concurring); *id.* at 331 (Stevens, J., dissenting). Removal of those artificial means is necessarily also within the scope of medical practice. And that removal is no less intended to end the life of the patient, a life that could be prolonged indefinitely in some cases, than is the provision of the drugs at issue here. *Glucksberg*, 521 U.S. at 743 (Stevens, J., concurring in the judgment). The same is true of "do not resuscitate" orders. While a line surely can be drawn between those procedures and the one at issue here, *Vacco v. Quill*, 521 U.S. 793, 800-05 (1997), that line is not properly drawn on the basis of what is and is not "medical."

Petitioners' assertion that assisting suicide is not "traditional" is focused at the wrong level of generality. This Court has not suggested that the States' historic regulatory powers are limited to doing only that which they have done at some indeterminate past time or that the proper inquiry is whether the specific case, matter, or practice at issue is within the States' historic powers. Rather, the Court consistently has protected state prerogatives in "traditionally sensitive *areas*." *Will*, 491 U.S. at 65 (emphasis added). Regulating the practice of medicine is one of those areas. And history has vindicated the recognition that "a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting); *accord Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring). The U.S. Attorney General's claim that everything new is not within the scope of the States' traditional powers would reduce that laboratory to a one-way ratchet in which the States could regulate more

stringently, but never stray beyond orthodoxy in any area upon which federal law touches.

Perhaps more significant than either of those considerations, however, is the simple fact of state sovereignty itself. This Court's consistent recognition that States "primarily and historically" have power "to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Medtronic*, 518 U.S. at 475 (citing cases), necessarily acknowledges that States have the sovereign's prerogative to determine what medical practices are and are not acceptable. None of the language Congress used in the CSA demonstrates unmistakably that Congress intended to reverse that longstanding recognition. To the contrary, the clues to legislative intent described above make it more likely that Congress intended to respect the States' sovereignty over the practice of medicine.

In *Raich*, of course, Congress unambiguously expressed its intention by placing marijuana on Schedule I. Here, by contrast, petitioners do not identify language in the CSA that clearly or unmistakably regulates or authorizes regulation of the specific practice permitted by the DWDA, of specific uses of any approved drug, or of specific medical practices. Rather, the statutory terms on which petitioners rely to support the claimed authority—"conduct which may threaten the public health and safety," "legitimate medical purpose," and "usual course of professional treatment"—are so elastic that accepting petitioners' construction would mean, as petitioners appear to embrace, that the Act permits the U.S. Attorney General to ban any particular use of any scheduled drug, Pet. Br. 29, and, apparently, to identify any disfavored medical practice and declare that no scheduled drug could be used for that purpose. And he can do so, they assert, without following any procedure or obtaining any scientific or medical input from the Secretary or anyone else. If that overstates the power

petitioners claim, they have not identified the principles that might limit it.

The DWDA is an expression of Oregon's "independent sovereign[ty]," *Medtronic*, 518 U.S. at 485, within the ambit of the State's historic power to regulate the practice of medicine. The U.S. Attorney General's threat to deregister or prosecute Oregon physicians and pharmacists who comply with the DWDA will necessarily deprive Oregonians of the rights embodied in that Act. Notwithstanding whether the U.S. Attorney General's threat is labeled as "preempting" the DWDA, it impinges on Oregon's exercise of its sovereignty in an area historically entrusted to the States. This Court unambiguously has refused to sanction similar federal action unless and until it has satisfied itself that Congress intended that result by including a clear statement of that intent, and the CSA does not contain that clear statement.

D. A clear statement is required here to support the U.S. Attorney General's threat because it would push the boundaries of Congress's authority under the Commerce Clause.

Just as intrusion on the States' historic powers calls for a clear statement of congressional intent, so, too, does administrative action at the margins of Congress's constitutional powers. *Solid Waste Agency*, 531 U.S. at 172-73. Here, the U.S. Attorney General seeks to regulate the doctor-patient relationship at the point where the doctor, acting in good faith and within the scope of affirmative state law, decides which among those medicines that concededly have approved uses he or she will prescribe to a patient to address the patient's specific medical needs. Such an action would be unprecedented and this Court previously has determined that Congress could not do as much. Resolution of that issue, moreover, must account for the negligible impact the DWDA would have on interstate commerce.

The Interstate Commerce Clause authorizes Congress to regulate in three general categories: Congress can regulate the channels of interstate commerce; it can regulate and protect the instrumentalities of interstate commerce, and persons or things in interstate commerce; and it can regulate activities that substantially affect interstate commerce. *Raich*, 125 S. Ct. at 2205 (citing *Perez v. United States*, 402 U.S. 146, 150 (1971), and *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937)). Only the third category could be at issue here. [18]

It then becomes necessary to isolate "the precise object or activity," *Solid Waste Agency*, 531 U.S. at 173, that the U.S. Attorney General seeks to regulate. The U.S. Attorney General's directive says nothing about either the commercial aspects of the doctor-patient transaction or the amount of drugs prescribed. That may be because those amounts are unremarkable. The drugs prescribed under the DWDA, primarily secobarbital and pentobarbital, Seventh Annual Report, at 14, concededly have accepted medical uses. Standard therapeutic doses of both range from 100 mg. as a sleeping aid to somewhat more or less than that daily for sedation.[19] A lethal prescription under the DWDA would involve nine or ten grams.[20] Consequently, many

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[18] Although it is likely that the drugs in question have traveled in interstate commerce, that alone is insufficient to support an exercise of the commerce power. *Jones*; *Lopez*.

[19] U.S. National Library of Medicine and National Institutes of Health, *Medline Plus*, http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202081.html (June 27, 2005)

[20] Oregon Department of Human Services, *Fifth Annual Report on Oregon's Death With Dignity Act*, 12-13 (2003); http://egov.oregon.gov/DHS/ph/pas/docs/year5.pdf.

prescriptions for conventional purposes would not differ significantly from a prescription provided to a terminally ill patient to end his or her life. Under the U.S. Attorney General's directive, therefore, the same prescription for the same drugs would be routine, on the one hand, or cause for prosecution, deregistration, or both, on the other, depending on the patient's and the physician's knowledge about the patient's intent. And while intent matters in the law, *Vacco*, 521 U.S. 800-05, whether Congress can regulate that intent under the Commerce Clause is quite a different question. [21] Consequently, the question becomes whether a physician's or patient's intentions about the ultimate use of the drugs substantially affect interstate commerce when the physician prescribes controlled substances for the purposes permitted the DWDA rather than more common therapeutic uses.

In *Raich*, the Court found *Wickard v. Filburn*, 317 U.S. 111 (1942), to be of "particular relevance." *Raich*, 125 S. Ct. at 2206. That case, the Court concluded, establishes that Congress can regulate noncommercial, intrastate activity if failure to do so would "undercut the regulation of the interstate market in that commodity." *Id.* Comparing the marijuana at issue in *Raich* with the wheat in *Wickard*, the Court concluded that although the federal interests at stake in the two cases differed, the potential for diversion of homegrown marijuana into the illegal market had the same

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[21] Petitioners note that the directive exempts physicians who treat pain associated with illness, "even though such treatment may have the unintended consequence of hastening the patient's death." Pet. Br. 20 n. 7. Even if hastening the patient's death is "unintended," it is a readily predictable consequence of the treatment to which they refer, which makes identifying precisely what the commerce power would be regulating even more difficult.

potential to frustrate the federal interest as the potential for diversion of wheat into the regulated market because each had a "substantial effect on supply and demand in the national market for that commodity." *Raich*, 125 S. Ct. at 2207 (footnote omitted). That conclusion was bolstered by the recognition that "in 2000 American users spent $10.5 *billion* on the purchase of marijuana." *Id.* at 2208 n. 31 (emphasis in original).

The actual or even hypothetical effects of the DWDA cannot rationally be considered comparable. Between 1998, when the DWDA was implemented, and 2004, the latest complete reporting period, 208 persons in Oregon died after ingesting a lethal dose of medication prescribed pursuant to that statute. Seventh Annual Report, 20. Even if all those patients had diverted their nine or ten grams of those drugs into whatever illegal market may exist for them, the amounts would be insignificant by any measure. Thus, it could not reasonably be asserted that implementing the DWDA could rip a "gaping hole" in the CSA, *Raich*, 125 S. Ct. at 2209, or that preventing its implementation is in any sense "essential to a comprehensive regulation of interstate commerce." *Id.* at 2217 (Scalia, J., concurring in the judgment).

The Court has explained on numerous occasions that it looks for a clear statement of Congress's intent to invoke the outer limits of its constitutional powers before the Court will decide whether Congress has reached or exceeded those limits. "[W]hen a particular interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. . . . Second, if an otherwise acceptable construction of a statute would raise serious constitutional problems, and where an alternative interpretation of the statute is fairly possible, . . . we are obligated to construe the statute to avoid such problems." *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001) (citations and

internal quotation marks omitted); *accord Jones*, 529 U.S. at 857 ("where a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter") (citation and quotation marks omitted). The rule is not observed merely to "avoid or postpone difficult decisions. The predominant consideration is that we should be sure Congress has intentionally put its power in issue by the legislation in question before we undertake a pronouncement which may have far-reaching consequences upon the powers of the Congress or the powers reserved to the several states." *United States v. Five Gambling Devices*, 346 U.S. 441, 448-49 (1953). And the Court assumes that "Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority." *Solid Waste Agency*, 531 U.S. at 172-73.

No one who follows this Court's Commerce Clause jurisprudence can fail to appreciate the significance to our federal system of the deep and abiding questions involved in *Garcia*, *Lopez*, *Morrison,* and *Raich*. That is not to suggest that all Commerce Clause cases present issues of such difficulty that the Court must always find a clear statement. But even where Congress has undoubted authority to regulate a subject matter area, profound questions can arise at the margins of that area. *Solid Waste Agency*, 531 U.S. at 172-74 (although Congress has Commerce Clause power to regulate navigable waters and some non-navigable waters, extending that power to isolated ponds would push the limit of congressional authority, thereby demanding "a clear indication Congress intended that result"). Although Oregon acknowledges, as it must, that Congress has the authority to regulate controlled substances generally, it rejects the contention that Congress could regulate the particular uses

that individual physicians, acting in good faith and pursuant to affirmative state law, can make of substances having accepted medical uses. *Linder v. United States*, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal government").[22] To grant the power claimed by the U.S. Attorney General here, the Court would, at a minimum, have to overrule *Linder* and, at worst, have to reopen the divisive question whether, even if state sovereignty is no shield against the full exercise of the Commerce Clause power, *Garcia*, all the limits on the reach of the federal sword have been identified. *E.g.*, *Jones*; *Morrison*; *Lopez*; *Printz v. United States*, 521 U.S. 898 (1997); *New York v. United States*, 505 U.S. 144 (1992). Avoiding just such difficult and potentially far-reaching questions until *Congress* unmistakably manifests its intention to raise them is a central reason for the clear statement requirement. *E.g.*, *Jones*, 529 U.S. at 858.

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[22] Petitioners argue that because *Linder* cited, among other cases, *Hammer v. Dagenhart*, 247 U.S. 251 (1918), it is a "*Lochner*-era" relic that has no continuing viability. To be sure, *Linder* relied on *Hammer*, but that case was merely one in a string citation that also included *McCulloch v. Maryland*, 4 Wheat. 316, 423 (1819). *Linder*, 268 U.S. at 17. Thus, even if part of *Linder*'s support is gone, the more important part certainly remains. And while this Court expressly overruled *Hammer*, it has not overruled *Linder*. To the contrary, years after the Court overruled *Hammer* in *United States v. Darby*, 312 U.S. 100, 116-17 (1941), the Court continued to cite *Linder* without suggesting that it lacked precedential value. *Robinson v. California*, 370 U.S. 660, 667 n. 8 (1962); *United States v. Kahriger*, 345 U.S. 22, 30 nn. 7 and 11 (1953), *overruled on other grounds Marchetti v. United States*, 390 U.S. 39, 54 (1968).

III. The Court should reject this unprecedented attempt by an agency official to resolve a disputed issue of social and medical policy that is reserved to the States and should reemphasize the vital role State sovereignty plays in our federal system and the need for Congress to speak clearly when it intends to interfere with that role.

Oregon understandably seeks to protect its sovereignty by ensuring that federal agents observe the limits of the power Congress intended to give them and that Congress observes the limits of its defined powers. Petitioners, perhaps equally understandably, appear determined to minimize the effect the Court should give to either of those limitations. In Oregon's view, this case is about statutory construction and about the principles that should guide that process when concerns of federalism and State sovereignty weigh heavily in the balance and the limits of Congress's power under the Commerce Clause are close by. Those concerns require that *Congress* have spoken with a clear voice and have made a clear statement of *Congress's* intent to infringe on the States' traditional powers. Yet petitioners can point to no clear statement in the CSA and must rely instead on ambiguous statutory language and administrative regulations and a directive purporting to interpret it.

In *Medtronic*, this Court determined that a federal statute did not bar the state-court, common-law tort actions at issue there despite the existence of "a statutory provision that expressly pre-empts state law." 518 U.S. at 484. The Court's interpretation of the statutory language was "informed by two presumptions about the nature of pre-emption." *Id.* at 485 (citation omitted). First, "because the States are independent sovereigns in our federal system, [the Court has] long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Id.* Particularly in areas where the

States' exercise "their police powers to guard the health and safety of their citizens," *id.* at 475, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 485 (internal quotation marks and citations omitted). Second, "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case" and congressional intent "primarily is discerned from the language of the" statute. *Id.* at 485-86 (internal quotation marks and citations omitted).

In contrast to *Medtronic*, where this Court found that federal law did not displace state common-law remedies despite the existence of an express preemption provision, petitioners seek to override the DWDA not only in the absence of such a provision, but in the face of an express anti-preemption provision in the CSA. They make that attempt in an area at the heart of the States' historic police powers and at or near the outer limits of Congress's power under the Commerce Clause. The vague and elastic statutory language on which petitioners are forced to rely simply cannot bear the weight they seek to place on it. Based on statutory language that does not at all reflect "the clear and manifest purpose of Congress" to intrude on the States' traditional power to regulate medicine, petitioners seek to corral that power and place it in the hands of the U.S. Attorney General. That attempt is sweeping in its implications. If it were to succeed, the States' historic powers would be compromised and their sovereignty undermined not only when a State takes a bold step like the one Oregon has taken with respect to end-of-life issues, but in more routine matters as well. That result should not be tolerated without a clear statement of congressional intent. Because the CSA contains no clear statement of congressional intent to usurp the States' authority to regulate

the practice of medicine, it follows that this Court should affirm.

CONCLUSION

This Court should affirm the judgment of the court of appeals.

Respectfully submitted,

HARDY MYERS
Attorney General of Oregon
PETER SHEPHERD
Deputy Attorney General
MARY H. WILLIAMS
Solicitor General
ROBERT M. ATKINSON
Assistant Attorney General
Counsel for Respondent
State of Oregon

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ALBERTO R. GONZALES,
ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF AMERICAN COLLEGE OF LEGAL MEDICINE, AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

MILES J. ZAREMSKI – *Counsel of Record*
KAMENSKY RUBINSTEIN HOCHMAN
AND DELOTT, LLP
7250 N. Cicero Avenue, Suite 200
Lincolnwood, Illinois 60712
Telephone: (847) 982-1776
Facsimile: (847) 982-1676

MAXWELL J. MEHLMAN
Arthur E. Petersilge Professor of Law
Director, THE LAW-MEDICINE CENTER
CASE SCHOOL OF LAW
Professor of Bioethics,
CASE SCHOOL OF MEDICINE
11075 East Boulevard
Cleveland, Ohio 44106
Telephone: (216) 368-3983

Attorneys for Amicus Curiae
American College of Legal Medicine

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

Whether the Attorney General has the unfettered right under the Controlled Substances Act to decide what is a legitimate medical purpose or use for determining parameters for medical intervention by physicians in the State of Oregon.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iii
INTEREST OF *AMICUS CURIAE*	1
SUMMARY OF ARGUMENT	2
ARGUMENT	4
I. THE CONTROLLED SUBSTANCES ACT DOES NOT GIVE THE ATTORNEY GENERAL THE POWER TO DETERMINE WHAT IS A LEGITIMATE MEDICAL PURPOSE	4
A. The Attorney General Improperly Invoked the "Public Interest" Evaluation under 21 U.S.C. § 824(a)	7
B. Court Decisions Uniformly Confirm That the Attorney General Must Defer to Medical Experts in Defining Legitimate Medical Use	9
II. THE REGULATION AND DETERMINATION OF LEGITIMATE MEDICAL PRACTICE IS RESERVED TO THE STATES	14
III. PROHIBITING THE USE OF NARCOTICS UNDER OREGON'S STATUTE WOULD NULLIFY THIS COURT'S DECISION IN *GLUCKSBERG*	17
IV. ALLOWING POLITICAL PREFERENCE TO DICTATE LEGITIMATE MEDICAL PRACTICE WOULD HARM THE MEDICAL PROFESSION AND THE PRACTICE OF MEDICINE	20
CONCLUSION	21

TABLE OF AUTHORITIES

	Page
CASES	
Arlen v. State Med. Bd., 399 N.E.2d 1251 (Ohio 1980)	12
Barsky v. Board of Regents, 347 U.S. 442 (1954)	16, 17
Chumbler v. McClure, 505 F.2d 489 (6th Cir. 1974)	13
Church v. Bloch, 182 P.2d 241 (Cal. 1947)	11
Cruzan v. Dir., Mo. Dept. of Health, 497 U.S. 261 (1990)	14
Davis v. Virginian Railway Co., 361 U.S. 354 (1960)	11
Dotson v. Tex. State Bd. of Med. Exam'rs, 612 S.W.2d 921 (Tex. 1981)	12
Downer v. Veilleux, 322 A.2d 82 (Me. 1974)	13
Farney v. Anderson, 372 N.E.2d 151 (Ill. 1978)	11
Gonzales v. Raich, ___ U.S. ___, 125 S.Ct. 2195 (2005)	5, 17
In re Williams, 573 N.E.2d 638 (Ohio 1991)	13
Linder v. United States, 268 U.S. 5 (1925)	14, 15, 16, 21
Loffredo v. Sobol, 600 N.Y.S.2d 507 (App. Div. 1993)	12
McKay v. State Bd. of Med. Exam'rs, 86 P.2d 232 (Colo. 1938)	12
Oregon v. Ashcroft, 192 F. Supp. 2d 1077 (D. Or. 2002)	2, 8
Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004)	*passim*
Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992)	19
Pennsylvania v. Union Gas Co., 491 U.S. 1 (1989)	15

TABLE OF AUTHORITIES – Continued

Page

People v. Klvana, 15 Cal. Rptr. 2d 512 (Ct. App. 1992) 11

Ramirez v. Tex. Bd. of Med. Exam'rs, 995 S.W.2d 915 (Tex. App. 1999) 21

Rudick v. Prineville Mem'l Hosp., 319 F.2d 764 (9th Cir. 1963) 11

Seminole Tribe v. Florida, 517 U.S. 44 (1996) 15

Smith v. Dep't of Registration, 106 N.E.2d 722 (Ill. 1952) 12

State v. Warden, 813 P.2d 1146 (Utah 1991) 11

Trawick v. Drug Enforcement Admin., 861 F.2d 72 (4th Cir. 1988) 8, 9

United States v. Bird, No. 95-20792, 1997 U.S. App. LEXIS 33988 (5th Cir. 1997) 15

United States v. Boettjer, 569 F.2d 1078 (9th Cir. 1978) 11

United States v. Moore, 423 U.S. 122 (1975) 10

United States v. Moore, 505 F.2d 426 (D.C. Cir. 1974) 10, 11

United States v. Morrison, 529 U.S. 598 (2000) 16

United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975) 10

United States v. Tran Trong Cuong, 18 F.3d 1132 (4th Cir. 1994) 11

Washington v. Glucksberg, 521 U.S. 702 (1997) ..... *passim*

White v. United States, 399 F.2d 813 (8th Cir. 1968) 11

Younger v. Harris, 401 U.S. 37 (1971) 14

TABLE OF AUTHORITIES – Continued

Page

STATUTES

21 U.S.C. § 811(b) 2, 4

21 U.S.C. § 811(e) 6

21 U.S.C. § 811(h) 6

21 U.S.C. § 812(b) 4

21 U.S.C. § 823(f) 8

21 U.S.C. § 824(a) 7, 9

21 U.S.C. § 824(a)(4) 7, 8

42 U.S.C. § 1395y 7

OTHER AUTHORITIES

66 Fed. Reg. 56,607 (Nov. 9, 2001) 2, 10

116 Cong. Rec. 33304 (Sept. 23, 1970) 6

Armin Ernst, M.D. and Joseph D. Zibrak, M.D., *Current Concepts: Carbon Monoxide Poisoning*, 399 New Eng. J. Med., Nov. 26, 1998 18

Brief of *Amici Curiae* Healthlaw Professors in Support of Respondents For Affirmance Of The Court and Opinion Below 13

David E. Joranson, *Guiding Principles of International and Federal Laws Pertaining to Medical Use and Diversion of Controlled Substances*, 131 NIDA Research Monograph at 14 (1993), *available at* http://www.medsch.wisc.edu/painpolicy/publicat/93nida.htm 5

TABLE OF AUTHORITIES – Continued

Page

Defendants' Memorandum In Support of Motion to Dismiss 13

FDA Approves Botox to Treat Frown Lines, FDA Talk Paper (U.S. Food and Drug Admin.), April 15, 2002, *available at* http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01147.html 7

"'Historic' change as opposition to euthanasia ends" (London) Daily Telegraph (July 5, 2005) (2005 WLNR 10348879) 14

Jim Barnett, *Kitzhaber Wants Direct Suicide Vote*, The Oregonian, March 1, 2000 13

Kathy Faber-Langendoen & Jason H.T. Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, 132 Annals Internal Med., Mar. 21, 2000 .... 18, 19

Linda Ganzini, M.D., et al., *Oregon Physicians' Attitudes About and Experience With End-of-Life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363, 2365 (May 9, 2001) 13

Louis Finkelstein Institute for Religious and Social Studies, *Physician Assisted Suicide Survey* (2005), *available at* The Jewish Theological Seminary, http://www.jtsa.edu/research/finkelstein/surveys/pas.shtml 14

Memorandum from Sheldon Bradshaw and Robert J. Delahanty, Office of Legal Counsel, Department of Justice, to the Attorney General (June 27, 2001) 10

TABLE OF AUTHORITIES – Continued

Page

Patricia M. Goode, *The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management*, Address Before the Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy (Mar. 17, 1998) (*available at* http://www.medsch.wisc.edu/painpolicy/domestic/dea98.htm) (last visited April 17, 2005) 12

Petitioner's Brief at 8, 19, 47, n.8 ..... 6, 7

S. Rep. No. 98-225 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182 ..... 8, 9

CONSTITUTIONAL PROVISIONS

U.S. Const. amend. X 3, 15, 16

U.S. Const. art. I, § 8, cl. 3 15

INTEREST OF *AMICUS CURIAE*

The American College of Legal Medicine ("ACLM") respectfully submits this brief as an *Amicus Curiae* pursuant to Rule 37 of the Rules of the Supreme Court of the United States. ACLM supports respondents in this case. ACLM has received the consent of all parties to submit this brief pursuant to the applicable rules of this Court.[1]

The ACLM has been in existence now for 45 years and is an educational, non-profit organization with nearly 1400 members. It is the only organization within the United States the majority of whose members possess degrees in medicine and in law. Its membership also consists of attorneys, physicians, nurses, persons in health care administration, in government service and those who hold full time academic positions in health care and in health care law. The ACLM is also part of the network of organizations worldwide whose members possess degrees, background, and interest in the fields of medicine, forensic science, and law or jurisprudence.

The mission of the ACLM is to educate, train and advance dialogue and discussion for those who have a sustained interest in issues at the crossroads of law, medicine, and health care delivery. This includes promoting the administration of justice and assisting jurists in deciding issues, such as those presented in this case.

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[1] Petitioners and respondents have consented to the filing of this brief in letters filed with the clerk. No counsel for a party authored this brief in whole or in part. No persons or entities other than the *amicus* made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The Attorney General, in a November 9, 2001 directive, declared that the use of controlled substances under the Oregon Death with Dignity Act was not a "legitimate medical purpose." *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1079 (D. Or. 2002) (quoting 66 Fed. Reg. 56,607 (Nov. 9, 2001)). This interpretation was promulgated in the Federal Register without prior notice to or comments by interested parties. *Oregon v. Ashcroft*, 368 F.3d 1118, 1130 (9th Cir. 2004). The Attorney General's controversial interpretation was based on lay opinion and a memorandum from the Justice Department entitled, *Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under The Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act* (June 27, 2001) ("OLC Opinion"). The Attorney General's statement represented a 180-degree shift in Drug Enforcement Administration ("DEA") policy and stood contrary to former Attorney General Janet Reno's position. *Oregon v. Ashcroft*, 368 F.3d at 1123. The Ninth Circuit held that, "the Attorney General has no specialized expertise in the field of medicine and that he imposes a sweeping and unpersuasive interpretation of the CSA . . . " *Id.* at 1130. This interpretation was made unilaterally and without the assistance of the Department of Health and Human Services ("HHS"), as required by the Controlled Substances Act ("CSA"). 21 U.S.C. § 811(b) (2005). The Ninth Circuit ruled that Attorney General Ashcroft had overstepped his bounds by making this determination and upheld the issuance of an injunction against the administration. *Oregon v. Ashcroft*, 368 F.3d at 1131.

We respectfully point out that the Attorney General's attempt to define "legitimate medical purpose" constitutes

a unilateral, uninformed, and politically-motivated action. The Attorney General does not have the authority, under the CSA, to make this determination. This determination is left to the states and the Secretary of HHS, informed by medical expertise. The Attorney General also failed to properly evaluate physician-assisted suicide under the "public interest" standard of the CSA. The Attorney General further failed to give due deference to input from the Oregon State Medical Board in assessing the five factors under the "public interest" standard of the CSA.

Instead of consulting the proper authority, the Attorney General has unilaterally determined what constitutes a "legitimate medical purpose" under the CSA. The federal government, however, has limited power under the CSA in making determinations of medical standards. Traditionally, states have regulated the practice of medicine as part of the police powers of the state. Allowing the enforcement of the Attorney General's view would also violate the Tenth Amendment, nullify this Court's opinion in *Washington v. Glucksberg*, 521 U.S. 702 (1997), and become a Damoclean sword unnecessarily held over the practice of medicine. The Attorney General's directive serves to invalidate Oregon's determination of a valid practice of medicine. If upheld, the opinion of a single administrative official could prevent physicians and patients from ensuring a pain-free and dignified end of life.

ARGUMENT

I. THE CONTROLLED SUBSTANCES ACT DOES NOT GIVE THE ATTORNEY GENERAL THE POWER TO DETERMINE WHAT IS A LEGITIMATE MEDICAL PURPOSE

Under the CSA, controlled substances are scheduled according to whether they have a "currently accepted medical use" or "no currently accepted medical use," with varying levels of restrictions. 21 U.S.C. § 812(b) (2005). The Act specifically delineates the manner in which drugs are scheduled and "accepted medical use" is determined. Integral to these determinations is the input of the Secretary of HHS. The Secretary's opinion is not simply advisory with respect to scheduling drugs, but binding. 21 U.S.C. § 811(b). The CSA states:

> [T]he recommendations of the Secretary to the Attorney General *shall be binding* on the Attorney General as to such *scientific and medical matters*, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.

Id. [emphasis added.]

Thus, the Attorney General can only make a determination of what is and is not a currently accepted medical use *based on a scientific and medical evaluation from the Secretary of HHS*. The Secretary must also include recommendations regarding where a substance should be scheduled. The recommendations of HHS are binding on the Attorney General as to scientific and medical matters, including where a drug is scheduled and whether or not a drug ought to be controlled.

The importance of the Secretary's input was acknowledged by this Court in its recent decision in *Gonzales v. Raich*, ___ U.S. ___, 125 S.Ct. 2195 (2005), where the Court noted that, under the CSA, the Attorney General must consult with the Secretary before updating and modifying the schedules of controlled substances. *Id.* at 2204. In *Gonzales*, this Court also noted that even Congress' decision to classify marijuana was based, in part, on the recommendation of the Department of Health and Human Services (then, the Department of Health, Education, and Welfare). *Id.*

The CSA does not give the Attorney General the authority to declare, *sua sponte*, what is and is not a currently accepted medical use. Instead, the Attorney General must defer to the expert medical judgment of HHS, embodied in a "scientific and medical evaluation." The history of the CSA highlights the legislative intent to preclude the Attorney General from making medical decisions. In a monograph of the National Institute on Drug Abuse, David E. Joranson states, "When Congress adopted the final version of the CSA in October 1970, the Secretary of Health, Education, and Welfare, and not the Attorney General, had been given the responsibility for making medical and scientific decisions concerning drug control." David E. Joranson, *Guiding Principles of International and Federal Laws Pertaining to Medical Use and Diversion of Controlled Substances*, 131 NIDA Research Monograph at 14 (1993), *available at* http://www.medsch.wisc.edu/painpolicy/publicat/93nida.htm. As Congressman Paul Rogers of the House Subcommittee on Health and the Environment stated:

> As Members may recall, the scientific and medical community of this nation were greatly upset

> over the fact that scientific and medical decisions in the Senate bill were centered in the Department of Justice, with the Attorney General having responsibility to make scientific and medical determinations which were not in the competency of the Department, and admittedly so. We have changed that so that the Department of Health, Education and Welfare will determine scientific and medical decisions. This is a most important change in the whole approach as it came from the Senate.

116 Cong. Rec. 33304 (Sept. 23, 1970).

The Attorney General's discretion is limited under the CSA. The Attorney General may determine whether to schedule a derivative drug in the same schedule or a higher numerical schedule than its immediate precursor. 21 U.S.C. § 811(e) (2005). And, if there is an imminent hazard to public safety, the Attorney General may move a controlled substance to Schedule I (no currently accepted medical use) for no more than eighteen months. 21 U.S.C. § 811(h) (2005). Neither of these decisions involves a determination of what is or is not a legitimate medical use.

The folly of the Attorney General's presumption that he can determine what is and is not a legitimate medical purpose for an approved drug is further illustrated by the mistaken assertions in his brief. The Attorney General argues that using controlled substances according to the Oregon Death with Dignity Act is not a legitimate medical purpose because it "does not aim to preserve the patient's health or to cure, alleviate, prevent, or 'treat' the disease or its symptoms in the patient." Petitioner's Brief at 19. The Attorney General thus confuses "legitimate medical purpose" with "therapeutic." Many legitimate medical interventions are not therapeutic. For example, the FDA

has approved the prescription use of botulism injection "to temporarily improve the appearance of moderate to severe frown lines between the eyebrows." *FDA Approves Botox to Treat Frown Lines*, FDA Talk Paper (U.S. Food and Drug Admin.), April 15, 2002, *available at* http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01147.html. This is a legitimate medical purpose, although its objective is cosmetic rather than to cure, alleviate, prevent, or treat disease. Indeed, the Attorney General's position would place the entire field of cosmetic surgery outside the legitimate practice of medicine, thereby making surgeons who employed controlled substances in the course of their cosmetic practice felons and at risk of losing their DEA registrations.

This same confusion is evident in the Attorney General's reliance on the fact that the Centers for Medicare and Medicaid Services of the Department of Health and Human Services has determined that physician-assisted suicide is not eligible for reimbursement under Medicare or Medicaid because it is "not reasonable and necessary for the diagnosis and treatment of disease or injury." Petitioner's Brief at 8, 47, n.18. Numerous legitimate medical interventions are not reimbursed under Medicare or Medicaid, including outpatient prescription drugs and routine physical checkups. 42 U.S.C. § 1395y.

A. The Attorney General Improperly Invoked the "Public Interest" Evaluation Under 21 U.S.C. § 824(a)

In 1984, the United States Congress amended the CSA by allowing the Attorney General to revoke licenses when registrants acted in a manner inconsistent with the "public interest." 21 U.S.C. § 824(a)(4) (2005). The Attorney

General, in this case, has attempted to use this power to prevent assisted suicide. In his 2001 opinion, the Attorney General warned that "administering federally controlled substances to assist suicide may 'render [a physician's] registration . . . inconsistent with the public interest and therefore subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4).'" *Oregon v. Ashcroft*, 192 F. Supp. 2d at 1079. As noted by the Ninth Circuit, the Attorney General impermissibly applied the "public interest" revocation standard by failing to properly evaluate the registrant's actions. *Oregon v. Ashcroft*, 368 F.3d at 1130.

The determination that a registrant's actions are "against the public interest" requires an assessment of five factors outlined in 21 U.S.C. § 823(f). *Trawick v. Drug Enforcement Admin.*, 861 F.2d 72, 75 (4th Cir. 1988). Paramount among these factors is the recommendation of the presiding state medical board. *Oregon v. Ashcroft*, 368 F.3d at 1129. The legislative history of this amendment stressed this fact, stating that "the Attorney General must 'continue to give deference to the opinions of the State licensing authorities,' as their recommendations are the 'first of the factors to be considered.'" *Id.* (quoting S. Rep. No. 98-225, at 267 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449.) However, "[i]t is undisputed that the Attorney General made no effort to solicit input from the State of Oregon before issuing his directive." *Id.* Accordingly, the Attorney General cannot assert that assisting suicide with controlled substances is against the public interest in Oregon because he has failed to perform the proper five-factor analysis necessary for making this conclusion.

In addition to ignoring the proper interpretation of the "public interest", the Attorney General's directive attempts

improperly to expand the scope of the CSA and the 1984 amendment. The CSA was enacted specifically to deal with "problems associated with drug abuse and addiction." *Id.* at 1128. The Attorney General's attempt to bar physician-assisted suicide is outside the scope of the act as "assisted suicide is not a form of drug abuse that Congress intended the CSA to cover." *Id.* at 1125.

The 1984 amendment similarly targets criminal diversion and abuse of drugs. The Attorney General's use of the amendment to bar assisted suicide is, again, beyond the scope of the act. The Fourth Circuit has held that 21 U.S.C. § 824(a) and the "public interest" standard were promulgated specifically to thwart criminal diversion of drugs. *Trawick*, 861 F.2d at 75. The Fourth Circuit also noted that "[t]he 'public interest' standard was added in 1984 in recognition of the specific weaknesses of the felony conviction criterion that made it difficult to reach the 'many violations involving controlled substances which are prescription drugs [but] are not punishable as felonies under state law.'" *Id.* (quoting S. Rep. No. 98-225 (1983)), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3448-49). Allowing the Attorney General to utilize 21 U.S.C. § 824(a) to bar assisted suicide would improperly expand the CSA and its 1984 amendment beyond the intended criminal scope.

B. Court Decisions Uniformly Confirm That the Attorney General Must Defer to Medical Experts in Defining Legitimate Medical Use

The CSA does not provide a definition of "legitimate medical purpose" in its extensive definitions. Court decisions, however, uniformly confirm that the Attorney General must defer to expert medical judgment in determining what is and is not a legitimate medical use. The

Attorney General relies on two cases in his brief, *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975) and *United States v. Moore*, 423 U.S. 122 (1975) for the proposition that the CSA prohibits physicians from prescribing drugs except for legitimate medical purposes. Both cases demonstrate that expert medical judgment is required in order to determine what is and is not a legitimate medical purpose. In *Rosenberg*, the Ninth Circuit held that Dr. Rosenberg violated the CSA by prescribing Schedule II, III and IV controlled substances to patients he had not examined. *Rosenberg*, 515 F.2d at 192. These actions were violations of the CSA because expert medical testimony showed that they were outside the "usual course of his professional practice." *Id.* at 199.

Moore was relied on by the Attorney General, 66 Fed. Reg. 56,607, and by the OLC Opinion. Memorandum from Sheldon Bradshaw and Robert J. Delahanty, Office of Legal Counsel, Department of Justice, to the Attorney General 5-6 (June 27, 2001). In *Moore*, a physician prescribed methadone, a Schedule II controlled substance, in large quantities, charging by the pill, to patients not in detoxification or maintenance programs. *United States v. Moore*, 505 F.2d 426, 447 (D.C. Cir. 1974). What is noteworthy is that expert medical opinion was necessary to prove that this was not a legitimate medical practice and, therefore, violated the CSA. 505 F.2d at 447-48 (MacKinnon, J., dissenting). Reversing the Court of Appeals, this Court held that the physician could be liable for failing to use controlled substances if prescribed outside the boundaries of "professional practice". *Moore*, 423 U.S. at 142. The Court's statement here affirmed the lower court's finding that expert testimony was required to demonstrate that the defendant's use of a drug [under the

CSA] was not " . . . consistent with any method . . . that is accepted by the medical profession in this country [citation omitted]." 505 F.2d at 447. Thus, requiring expert medical testimony in a case predicated on violations of the CSA equates to determining legitimate medical use or purpose.

Other cases as well support the position that expert medical knowledge is required in all jurisdictions to determine legitimate medical use for purposes of proving that a physician has violated the CSA in the course of professional practice. "The general rule is that the propriety or impropriety of particular medical treatment can be established only by expert medical testimony." *Church v. Bloch*, 182 P.2d 241, 245 (Cal. 1947). *See also United States v. Boettjer*, 569 F.2d 1078, 1079 (9th Cir. 1978); *Farney v. Anderson*, 372 N.E.2d 151, 154 (Ill. 1978); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137-38 (4th Cir. 1994); and *White v. United States*, 399 F.2d 813, 820 (8th Cir. 1968). Additionally, this required deference is consistent with the manner in which the law establishes what is and is not a legitimate medical use in contexts outside of the CSA. This Court, in *Davis v. Virginian Railway Co.*, 361 U.S. 354 (1960), articulated the standard of proof for malpractice as requiring two elements of evidence, " . . . evidence as to the recognized standard of care of the medical community in the particular kind of case, and a showing that the physician in question negligently departed from this standard in his treatment of the plaintiff." *Id.* at 357. Expert medical testimony is necessary to prove both elements. *See State v. Warden*, 813 P.2d 1146, 1151 (Utah 1991); *People v. Klvana*, 15 Cal. Rptr. 2d 512, 536 (Ct. App. 1992); and *Rudick v. Prineville Mem'l Hosp.*, 319 F.2d 764 (9th Cir. 1963). Expert medical knowledge, whether from outside experts or based on the expertise of

the physician members of the state medical boards, is also necessary to determine what is and is not a legitimate medical use in disciplinary hearings before state medical boards. *See Dotson v. Tex. State Bd. of Med. Exam'rs*, 612 S.W.2d 921, 923 (Tex. 1981); *Loffredo v. Sobol*, 600 N.Y.S.2d 507, 509-10 (App. Div. 1993); *McKay v. State Bd. of Med. Exam'rs*, 86 P.2d 232, 236 (Colo. 1938); *Smith v. Dep't of Registration*, 106 N.E.2d 722, 730-31 (Ill. 1952); and *Arlen v. State Med. Bd.*, 399 N.E.2d 1251, 1254 (Ohio 1980). The Texas Supreme Court in *Dotson* reversed a medical board's decision to suspend a doctor's license because there was no expert testimony to support the Board's factual conclusions. *Dotson*, 612 S.W.2d at 923.

Both the Attorney General and the DEA also appear to recognize the appropriateness of deferring to expert medical judgment. The DEA has recognized the need for experts to dictate and define "legitimate medical purpose." Patricia M. Goode, Chief of the Liaison and Policy Section of the DEA, told the Federation of State Medical Boards in a 1998 speech that, "[t]he CSA by design does not define "legitimate medical purpose" nor does it set forth standards of medical practice. These issues can only be defined by the medical community and its internal review process." Patricia M. Goode, *The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management*, Address Before the Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy (Mar. 17, 1998) (*available at* http://www.medsch.wisc.edu/painpolicy/domestic/dea98.htm) (last visited April 17, 2005). The Attorney General referred to the American Medical Association's (AMA's) and the American Nurses Association's (ANA's) opinions opposing the Oregon Death with Dignity Act. Defendants' Memorandum In Support of Motion to

Dismiss at 34. However, it is important to note that the AMA's and ANA's views, themselves, do not settle the question of what is a legitimate medical use. The law recognizes that the practice of medicine is complex and that reasonable physicians may differ on what is legitimate and appropriate. There is room for disagreement among reasonable practitioners, as is reflected in the "respectable minority doctrine," which recognizes medical practices that are not the norm but are, nonetheless, legitimate in that they are acceptable and supported by a school of expert medical thought. *In re Williams*, 573 N.E.2d 638 (Ohio 1991); *Chumbler v. McClure*, 505 F.2d 489, 492 (6th Cir. 1974); and *Downer v. Veilleux*, 322 A.2d 82, 87 (Me. 1974).

More importantly, a majority of Oregon physicians believe that the Oregon Death with Dignity Act is consistent with legitimate medical practice. A survey from the *Journal of the American Medical Association* found that 51% of responding Oregon physicians (66% of practicing Oregon physicians) strongly supported or support the Death with Dignity Act and legalization of physician-assisted suicide. Linda Ganzini, M.D., et al., *Oregon Physicians' Attitudes About and Experience With End-of-Life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363, 2365 (May 9, 2001). Supporters include Governor of Oregon, John A. Kitzhaber, M.D. Jim Barnett, *Kitzhaber Wants Direct Suicide Vote*, The Oregonian, March 1, 2000, at A03. According to studies, Oregonians and health care professionals also found assisted suicide being requested for sound and thoughtful reasons, without this method of terminating life being imposed upon patients. Br. *Amici Curiae* Healthlaw Professors, at 9-11, 14-15.

A national survey also established that 57% of U.S. physicians support physician-assisted suicide. Louis Finkelstein Institute for Religious and Social Studies, *Physician Assisted Suicide Survey* (2005), *available at* The Jewish Theological Seminary, http://www.jtsa.edu/research/finkelstein/surveys/pas.shtml. Even professional medical views recently adopted outside this country support not advocating against assisted suicide. "'Historic' change as opposition to euthanasia ends" (London) Daily Telegraph (July 5, 2005) (2005 WLNR 10348879). (Long-standing opposition among doctors to euthanasia dropped by the British Medical Association.).

II. THE REGULATION AND DETERMINATION OF LEGITIMATE MEDICAL PRACTICE IS RESERVED TO THE STATES

In Justice O'Connor's concurring opinion in *Glucksberg*, this Court recognized that the legality of physician-assisted suicide was an issue reserved to the "'laboratory' of the States in the first instance" and that states were undertaking extensive and serious evaluation of such issues. *Glucksberg*, 521 U.S. at 737 (quoting *Cruzan v. Dir., Mo. Dept. of Health*, 497 U.S. 261, 292 (1990)). The Court noted as well, "Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735. Further, in past cases this Court has noted that the regulation and licensing of medical practices is generally reserved to the states under the United States Constitution. *See Linder v. United States*, 268 U.S. 5, 18 (1925); and *Younger v. Harris*, 401 U.S. 37, 44-45 (1971). In *Linder*, this Court reversed a physician's conviction under the Harrison Anti-Narcotic Law as outside the scope of the purpose of revenue collection. *Linder*, 268

U.S. at 22. This Court held that, "direct control of medical practice in the States is beyond the power of the federal government." *Id.* at 18. Allowing the Attorney General to dictate and define "legitimate medical purpose" would permit the federal government impermissibly to expand the scope of the CSA and exercise direct control over the practice of medicine in Oregon.

Although the CSA regulates the dispensing of medications under the Interstate Commerce Clause (U.S. Const. art. I, § 8, cl. 3), the Tenth Amendment (U.S. Const. amend. X), in addition to the stated purpose of the CSA, limits its power. As noted in the legislative history of the CSA, the State must be given deference to determine medical standards and licensing under its police power. *Oregon v. Ashcroft*, 368 F.3d at 1128. The dissenting judge in the Ninth Circuit did note that activities restricting prescription of controlled substances under the CSA are borne of Constitutional authority under the Interstate Commerce Clause. *Id.* at 1142. Such authority, however, does not always trump antecedent Amendments. *Seminole Tribe v. Florida*, 517 U.S. 44, 65 (1996). This Court, interpreting constitutional construction, stated that it could not accept "limitation of the principle embodied in the Eleventh Amendment through appeal to antecedent provisions of the Constitution." *Id.* (quoting *Pennsylvania v. Union Gas Co.*, 491 U.S. 1, 42 (1989) (Scalia, J., dissenting)). Similarly, the Tenth Amendment cannot be completely limited by the antecedent provisions of the Commerce Clause. *Id.* Though the scope of the Commerce Clause has been extensive and often used to interfere with intrastate police power, this power is not limitless. *United States v. Bird*, No. 95-20792, 1997 U.S. App. LEXIS 33988, at *23 n.10 (5th Cir. 1997). In *Bird*, The Fifth Circuit warned that, though "[t]he Tenth Amendment contains no substantive restriction on the legitimate exercise of Congress's

Commerce Clause authority . . . the Tenth Amendment plainly *does* confirm that the commerce power is *not* limitless, that hence such boundaries *do* exist, and that they *must not* be transgressed." *Id.* Our federal system precludes the Commerce Clause from becoming an excuse for the federal government to infringe upon state sovereignty and traditional state power. The Commerce Clause should not be utilized by one federal official to justify such a violation.

Allowing the Attorney General to define "legitimate medical purpose" and, in so doing, bar physician-assisted suicide, would be an unconstitutional invasion of the State of Oregon's police power. As *Linder* held, direct control of medical practice is outside the province of the federal government. *Linder*, 268 U.S. at 18. This Court took the same view when striking down a federal statute prohibiting gender-motivated crimes of violence. *United States v. Morrison*, 529 U.S. 598, 617-18 (2000). The majority in *Morrison* held that the Commerce Clause should not be utilized to usurp the proper police power of the states. *Id.* This Court stated, "[w]e accordingly reject the argument that Congress may regulate noneconomic, violent criminal conduct based solely on that conduct's aggregate effect on interstate commerce. The Constitution requires a distinction between what is truly national and what is truly local." *Id.* Oregon's Death with Dignity Act is both substantively and geographically a truly local law because its impact and operation do not survive outside Oregon's borders.

Regulation of the practice of medicine, like the suppression of violent crime, is part of the police power of the state. As noted by this Court in *Barsky v. Board of Regents*, 347 U.S. 442 (1954), "[i]t is elemental that a state

has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power." *Id.* at 449. The Attorney General's directive is an attempt to infringe this police power and thwart the state of Oregon's right to regulate health care as it sees fit. This Court should not allow the federal government to interfere with this state law.

Finally, this court's recent decision in *Gonzales v. Raich*, at 5, is consistent with our position. In that case, this court correctly determined that a California law could not avoid the CSA's classification of marijuana as a Schedule I substance. The Court stated that the CSA extended to regulation of drugs " . . . produced and consumed locally." *Gonzales*, ___ U.S. ___, 125 S.Ct. at 2201. In contrast, the current matter does not address whether a locally produced medication is governed by the CSA. Rather, it concerns whether the Attorney General may use his position to dictate how a drug regulated by the CSA can be used in medical practice by Oregon physicians. Such determinations are beyond the scope of the Attorney General's statutory power.

III. PROHIBITING THE USE OF NARCOTICS UNDER OREGON'S STATUTE WOULD NULLIFY THIS COURT'S DECISION IN *GLUCKSBERG*

Allowing the Attorney General to disregard states' rights here would invalidate this Court's decision in *Glucksberg*. If the Attorney General could prohibit the dispensing of narcotics for use in assisted suicide, he, alone, would essentially nullify this Court's determination that states could permit these practices. *Glucksberg*, 521 U.S. at 735.

In the present case, the dissent in the court below argued that the effect of the Attorney General's directive is minimized by the mere availability of other methods of assisting suicide. *Oregon v. Ashcroft*, 368 F.3d at 1135 (Wallace, J., dissenting). This reasoning gives short shrift to the issue and ignores the true effects of the Attorney General's rule. Utilization of controlled narcotics in hastening death may represent the most humane manner of effectuating a patient's directive of death by physician assistance. Kathy Faber-Langendoen & Jason H.T. Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, 132 Annals Internal Med., Mar. 21, 2000, at 482-87. Judge Wallace points to a law review article that suggests carbon monoxide poisoning as an alternative method of suicide. *Oregon v. Ashcroft*, 368 F.3d at 1135. However, this suggestion ignores the fact that this toxin is not used by any physicians for any legitimate medical purpose. Armin Ernst, M.D. and Joseph D. Zibrak, M.D., *Current Concepts: Carbon Monoxide Poisoning*, 399 New Eng. J. Med., Nov. 26, 1998, at 1603-1608. Carbon monoxide is not an FDA-approved medication and has no current bona fide use in the medical field. Physician inexperience with carbon monoxide administration may result in failed suicide attempts. Faber-Langendoen & Karlawish, *supra*, at 482-87. Additionally, carbon monoxide poisonings, in contrast to narcotic overdoses, may result in significant pain and suffering during a patient's death. Ernst & Zibrak, *supra*, at 1603-1608. (noting significant acute symptoms from carbon monoxide poisoning including headache, nausea, shortness of breath, chest pain and abdominal pain). Failed attempts at poisoning may also result in significant neurological deficits. Up to 30% of surviving carbon monoxide poisoning victims experience a neuropsychiatric syndrome up to 240 days after poisoning.

Id. Symptoms may include psychosis, dementia, personality change, incontinence and parkinsonism. *Id.* As a result, and despite Judge Wallace's suggestions to the contrary, this form of assisted suicide is not an effective substitute for assisted suicide with controlled substances. It would be reckless for this Court to approve all manners of terminating life as the practice of medicine. Allowing all methods of poisoning to achieve such a result within the ambit of medical practice would also set a broad and dangerous precedent that may damage the medical profession.

Narcotics remain integral to providing sedation and pain control in current forms of physician-assisted suicide. Faber-Langendoen & Karlawish, *supra*, at 482-87. Enforcement of the Attorney General's directive may completely prohibit the administration of these controlled substances, causing a painful and angst-ridden demise. This prohibition directly infringes on liberty interests implied in the *Glucksberg* ruling. As Justice Stevens pointed out in his concurring opinion, "[a]voiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly 'at the heart of [the] liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life.'" *Glucksberg*, 521 U.S. at 745. (Stevens, J., concurring) (quoting *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 851 (1992)). As a result, the Attorney General's restricting the states' ability to allow a dignified and pain-free death unconstitutionally violates the liberty interests of an entire class of Oregonians.

IV. ALLOWING POLITICAL PREFERENCE TO DICTATE LEGITIMATE MEDICAL PRACTICE WOULD HARM THE MEDICAL PROFESSION AND THE PRACTICE OF MEDICINE

Allowing politically-appointed administrators to dictate proper medical practices would harm the integrity and stability of the medical field. As noted in *Glucksberg*, the integrity of the practice of medicine is important and, "the state also has an interest in protecting the integrity and ethics of the medical profession." *Id.* at 731. Allowing the standard of care to be subject to mercurial political whim could have devastating consequences on this profession.

As noted in the Ninth Circuit's opinion, Attorney General Janet Reno refused to declare assisted suicide as a violation of the CSA. *Oregon v. Ashcroft*, 368 F.3d at 1123. Instead, Attorney General Reno made it clear that, "the CSA was not 'intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice.'" *Id.* A subsequent political regime change reversed this position. If this Court were to uphold such a reversal, the determination of "legitimate medical practice" would face continuous revision depending on the prevailing politics in the executive branch. This uncertainty was noted by the dissent in the Ninth Circuit who stated, "[a] change in presidential administrations or a shift in the current President or Attorney General's perspective might precipitate the Ashcroft Directive's rescission." *Id.* at 1148. This uncertainty in the standards of practice cannot be allowed.

Medical practice must be determined by objective standards of care and clinically-based studies. Judicially,

"[w]hat constitutes bona fide medical practice must be determined upon consideration of evidence and attending circumstances." *Linder*, 268 U.S. at 18. Scientific journals, specialty boards, and peer review must dictate standards of practice, not partisan politicians. It is in recognition of the need for this expertise that every state's legislature has ceded part of its police power to expert medical boards and those with requisite medical expertise. Additionally, recognition of this expertise has prompted state courts to afford great discretion to board decisions. *Ramirez v. Tex. Bd. of Med. Exam'rs*, 995 S.W.2d 915, 919 (Tex. App. 1999). Allowing the will of politically-motivated officials to circumvent proper oversight and regulation by health care and medical professionals would serve to undermine the medical profession.

CONCLUSION

In conclusion, the plain language of the CSA, its accompanying legislative history, and the cases interpreting its provisions make it clear that determining a legitimate medical purpose is a matter of expert medical judgment, not a political decision by the Attorney General. The statutory scheme requires the Attorney General to defer to the Secretary of Health and Human Services, informed by appropriate and sound medical expertise, and to not act with a Draconian hand as he has chosen to do by issuing the directive at issue in this case. Moreover, as Justice O'Connor wisely observed in this Court's *Glucksberg* decision, the states are the proper laboratories to experiment with adjusting the scope of acceptable medical practice. The State of Oregon has done so with its Death

With Dignity Act. Its decision should be followed and respected by this Court.

For the foregoing reasons, the judgment of the Ninth Circuit should be affirmed.

Respectfully submitted,

MILES J. ZAREMSKI – *Counsel of Record*
KAMENSKY RUBINSTEIN HOCHMAN
AND DELOTT, LLP
7250 N. Cicero Avenue, Suite 200
Lincolnwood, Illinois 60712
(847) 982-1776

MAXWELL J. MEHLMAN
Arthur E. Petersilge Professor of Law
Director, THE LAW-MEDICINE CENTER
CASE SCHOOL OF LAW
Professor of Bioethics,
CASE SCHOOL OF MEDICINE
11075 East Boulevard
Cleveland, Ohio 44106
(216) 368-3983

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Petitioners,

v.

STATE OF OREGON, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

RONALD A. LINDSAY
SEYFARTH SHAW LLP
815 Connecticut Ave., N.W.
Suite 500
Washington, D.C. 20006
(202) 463-2400

REBECCA P. DICK *
DAVID SONTAG
DECHERT LLP
1775 Eye St., N.W.
Washington, D.C. 20006
(202) 261-3500

* Counsel of Record

AMICI CURIAE: MARGARET P. BATTIN, TOM L. BEAUCHAMP, DAN W. BROCK, AND EDWARD LOWENSTEIN; S. JAMES ADELSTEIN, ANITA L. ALLEN-CASTELLITTO, MARCIA ANGELL, ROBERT ARNOLD, JOHN D. ARRAS, CHARLES H. BARON, HOWARD BRODY, ROBERT V. BRODY, ALLEN BUCHANAN, NORMAN L. CANTOR, ARTHUR L. CAPLAN, CHRISTINE K. CASSEL, ERIC J. CASSELL, R. ALTA CHARO, ROBERT COOK-DEEGAN, NORMAN DANIELS, NANCY NEVELOFF DUBLER, RONALD DWORKIN, RUTH FADEN, DANIEL D. FEDERMAN, JOEL E. FRADER, LESLIE PICKERING FRANCIS, JOHN M. FREEMAN, BERNARD GERT, SAMUEL GOROVITZ, JEFFREY KAHN, YALE KAMISAR, JEROME P. KASSIRER, SYLVIA LAW, ROBERT S. LAWRENCE, ROBERT J. LEVINE, CHARLES F. MCKHANN, ALAN MEISEL, DAVID ORENTLICHER, TIMOTHY E. QUILL, ARNOLD S. RELMAN, BEN A. RICH, JOHN A. ROBERTSON, THOMAS M. SCANLON, LAWRENCE J. SCHNEIDERMAN, ANITA SILVERS, PETER SINGER, BONNIE STEINBOCK, JEREMY SUGARMAN, JUDITH J. THOMSON, ROBERT D. TRUOG, SIDNEY H. WANZER, RICHARD A. WASSERSTROM, WILLIAM J. WINSLADE, AND PETER M. WINTER

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTION PRESENTED

Does the Controlled Substances Act authorize the Attorney General to determine that prescribing a controlled substance for the purpose of enabling a mentally competent, terminally ill patient to secure assistance in dying is never within "the course of professional practice," even though such care is expressly authorized by state law?

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
INTEREST OF *AMICI CURIAE*	1
SUMMARY OF ARGUMENT	2
ARGUMENT	6
I. WRITING A PRESCRIPTION PURSUANT TO OREGON'S DEATH WITH DIGNITY ACT IS WITHIN "THE COURSE OF PROFESSIONAL PRACTICE" AND "THE LEGITIMATE PRACTICE OF MEDICINE"	6
A. Medical Practice Encompasses a Range of Humane Care	6
B. Many United States Physicians Today Consider Assistance in Hastening Death To Be Within "the Course of Professional Practice" in Some Cases	9
C. Many Competent Patients Consider Physician Assistance in Hastening Death To Be Within the Range of Care They Should Be Able To Obtain from Their Physicians	14
II. OREGON'S DEATH WITH DIGNITY ACT DOES NOT THREATEN THE PUBLIC HEALTH AND SAFETY	16
A. There Is No Evidence That the Oregon Statute Has Harmed the Public Health and Safety	16
B. The Oregon Statute Has Provided the Benefits Expected by Oregon Voters	17

TABLE OF CONTENTS—Continued

	Page
C. The Oregon Statute Has Also Brought Unexpected Benefits	19
D. Dangers That Exist Elsewhere Are Avoided in Oregon	20
III. THE CONTROLLED SUBSTANCES ACT APPROPRIATELY PRESERVES STATE AUTHORITY OVER MANY ASPECTS OF MEDICAL PRACTICE, INCLUDING THE USE OF CONTROLLED SUBSTANCES IN MEDICAL TREATMENT AT THE END OF LIFE	20
A. The Controlled Substances Act Aims To Curb Drug Trafficking, Preserving State Authority Except in Cases of a "Direct Conflict" with the Federal Act	20
B. Significant Aspects of the Medical Use of Controlled Substances Have Remained Free of Federal Control	23
C. The Attorney General Could Apply His Interpretation To Interfere With Many Other Forms of End-Of-Life Medical Care, Including Palliative Care and Refusals of Treatment	25
D. The Interpretive Rule Also Intrudes on Other State Authority	26
CONCLUSION	29

TABLE OF AUTHORITIES

CASES	Page
Bowen v. American Hosp. Ass'n, 476 U.S. 610 (1986)	21
Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261 (1990)	8, 14, 18, 27
Davis v. Michigan Dep't of Treasury, 489 U.S. 803 (1989)	9
FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)	9
In re Quinlan, 70 N.J. 10 (1976)	8, 14
Schiavo v. Schiavo, No. 05-11628, slip op. (11th Cir. March 25, 2005), *available at* http://www.ca11.uscourts.gov/opinions/ops/200511628.pdf	8
United States v. Moore, 423 U.S. 122 (1975)	10, 21
United States v. Moore, 505 F.2d 426 (D.C. Cir. 1974)	10
United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975)	21
U.S. v. Tran Trong Cuong, M.D., 18 F.3d 1132 (4th Cir. 1994)	10
Washington v. Glucksberg, 521 U.S. 702 (2001)	7, 8, 15, 16, 28
FEDERAL STATUTE	
Controlled Substances Act, 21 U.S.C. 801-971 (2004)	*passim*
FEDERAL REGULATION AND INTERPRETIVE RULE	
21 C.F.R. 1306.04(a) (2004)	9, 13, 22
Interpretive Rule, AG Order No. 2534-2001 (Nov. 9, 2001)	22

TABLE OF AUTHORITIES—Continued

CONGRESSIONAL REPORT — Page

H.R. Rep. No. 91-144, 1970 U.S.C.C.A.N. 4575.. 21

FEDERAL COURT PLEADINGS

Schiavo v. Schiavo, No. 8:05-CV-530-T-27TBM, Statement of Interest of the United States, March 21, 2005 (M.D. Fla.), *available at* http://news.findlaw.com/hdocs/docs/schiavo/32105dojstmnt.pdf 26

STATE STATUTES

Me. R. 02-373-011, § 3 *available at* ftp://ftp.maine.gov/pub/sos/cec/rcn/apa/02/373/373c011.doc. 24

Nev. Admin. Code 630.187 (2004), *available at* http://www.leg.state.nv.us/NAC/NAC-630.html#NAC630Sec187 23

Oregon Death With Dignity Act, Or. Rev. Stat. 127.800-995 (2003), *available at* http://www.leg.state.or.us/ors/127.html ..... *passim*

Or. Rev. Stat. 677.474 (2003), *available at* http://www.leg.state.or.us/ors/677.html 23

R.I. Gen. Laws Tit. 5, 5-37.4, *available at* http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.4/INDEX.HTM 25

PROPOSED STATE LEGISLATION

H.R. 2313, 47th Leg., 1st Reg. Sess. (Ariz. 2005), *available at* http://www.azleg.state.az.us/FormatDocument.asp?inDoc=/legtext/47leg/1r/bills/hb2313p%2Ehtm&DocType=B 27-28

Assemb. 654, 2005-06 Reg. Sess. (Cal. 2005), *available at* http://info.sen.ca.gov/pub/bill/asm/ab_0651-0700/ab_654_bill_20050526_amended_asm.pdf 28

TABLE OF AUTHORITIES—Continued

Page

H.R. 1454, 23rd Legis. (Haw. 2005) *available at* http://www.capitol.hawaii.gov/sessioncurrent/bills/hb1454_.htm 28

H.R. 168, 68th Biennial Sess. (Vt. 2005), *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/bills/intro/H-168.HTM ... 28

Assemb. 348, 96th Leg. Sess., 2003-04 Reg. Sess. (Wis. 2003), *available at* http://www.legis.state.wi.us/2003/data/AB-348.pdf 28

S. 7, 57th Leg., 2004 Budget Sess. (Wy. 2004), *available at* http://legisweb.state.wy.us/2004/introduced/SF0007.pdf 28

ARTICLES, BOOKS, MODEL GUIDELINES, AND REPORTS

Ancient Medicine: Selected Papers of Ludwig Edelstein (Owsei Temkin and C. L. Temkin eds. 1987) 22-23

J. Beck & E. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug Law Journal 71 (1998) 23

E. Emmanuel, *et al.*, *Attitudes and Desires Related to Euthanasia and Physician-Assisted Suicide Among Terminally Ill Patients and Their Caregivers*, 284 J. American Med. Ass'n 2460 (2000) 20

E. Emanuel, *et al.*, *Euthanasia and Physician-assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 Lancet 1805 (1996) 21

TABLE OF AUTHORITIES—Continued

Page

Federation of State Medical Boards of the United States, Inc., *Model Guidelines* for *the Use of Controlled Substances for the Treatment of Pain* (1998), a*vailable at* http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/model_pain_guidelines.htm 22

Louis Finkelstein Institute for Social and Religious Research and HCD Research, *Physician-Assisted Suicide Survey* (March 2005), *available at* http://www.jtsa.edu/research/finkelstein/surveys/pas.shtml 10-11

L. Ganzini, *et al., Oregon Physicians' Attitudes About and Experiences With End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 J. American Med. Ass'n 2363 (2001) 19

D. Joranson, *et al., Pain Management and Prescription Monitoring*, 23 J. Pain and Symptom Management 231 (2002) 24

K. Jost, *Right to Die*, 15 CQ Researcher No. 18 at 428 (2005) 15

A. C. Kao and K. P. Parsi, *Content Analyses of Oaths Administered at U. S. Medical Schools in 2000*, 79 Academic Medicine 882 (2004) 13

M. McCauley, *Taking a Look at 2004* at 2, Table: Hospice Penetration Rates (Or. Hospice Ass'n Newsletter 2005), a*vailable at* http://www.oregonhospice.org/graphics/pdfs/2004newsletters0305.pdf 19

TABLE OF AUTHORITIES—Continued

Page

D. E. Meier, *et al., A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 New Eng. J. Med. 1193 (1998) 12

F. Miller, *et al., Regulating Physician-Assisted Death,* 331 N. Eng. J. Med. 119 (1994) 11

New York State Task Force on Life and the Law, *When Death Is Sought: Assisted Suicide and Euthanasia in the Medical Context* (May 1994), *available at* http://www.health.state.ny.us/nysdoh/provider/death.htm 11, 12

K. Novielli, *Correlates of Physicians' Endorsement of the Legalization of Physician-assisted Suicide*, 75 Academic Medicine S53 (2000) 11

Oregon Dep't of Human Services, Seventh Annual Report on Oregon's Death With Dignity Act (2005), *available at* http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf 16

T. Quill and C. Cassel, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138 Annals of Internal Medicine 208 (2003) 11

T. Quill, B. Coombs Lee, and S. Nunn, *Palliative Treatments of Last Resort: Choosing the Least Harmful Alternative*, 132 Annals of Internal Medicine 488 (2000) 7-8

T. Quill, B. Lo, and D. Brock, *Palliative Options of Last Resort: A Comparison of Voluntarily Stopping Eating and Drinking, Terminal Sedation, Physician-Assisted Suicide and Voluntary Active Euthanasia* 278 J. American Med. Ass'n 2099 (1997) 11

TABLE OF AUTHORITIES—Continued

Page

J. Rhymes, *Hospice Care in America*, 264 J. American Med. Ass'n 369 (1990) 8

St. Louis University and American Society of Law, Medicine & Ethics, State Pain Policies [and] Regulations, *available at* http://www.painandthelaw.org/statutes/painpolicy_regulations.php 24

L. R. Slome, *et al.*, *Physician-Assisted Suicide and Patients with Human Immunodeficiency Virus Disease*, 336 N. Eng. J. Med. 417 (1997)..... 12

IN THE

Supreme Court of the United States

No. 04-623

ALBERTO GONZALES, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

STATE OF OREGON, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICI CURIAE* [1]

Amici curiae are physicians, attorneys, and professors who address issues of medical ethics in their work. Their names, titles, and main institutional affiliations are listed in the Appendix. Each has studied the ethics of care for patients at the end of life. In the view of *amici*, the "course of professional practice" can include medical assistance for a mentally competent, terminally ill patient who seeks help in dying. *Amici*

[1] No one other than the named *amici* and their counsel wrote this brief in whole or in part, or made any monetary contribution to its preparation. The parties' written consents to the filing of this brief are being filed with the Clerk herewith.

also find the Attorney General's 2001 interpretive rule to be an inappropriate and legally insupportable assertion of federal authority over aspects of the practice of medicine that are the province of state law.

SUMMARY OF ARGUMENT

1. A physician's ongoing care for a mentally competent, terminally ill patient appropriately includes, if the patient so wishes and local law permits, assistance in enabling the patient to manage the time and manner of death. Such assistance is part of a continuum of humane medical care that begins with efforts to cure the patient and alleviate pain and suffering. If recovery becomes so unlikely that, in the patient's view, the burdens of continued attempts at a cure outweigh their benefits, then the physician redirects the course of treatment to meet the patient's wishes, while continuing to try to relieve pain and suffering. If, despite these efforts, the expected outcome is a physical or mental decline that the patient finds so repugnant, demeaning, or painful that an earlier death becomes preferable, then the physician may appropriately provide a patient who so requests with a drug to hasten death. The patient can then decide whether or not to ingest it. These forms of medical care have as their common core the physician's deep concern for the patient's well-being, informed by an understanding of the patient's convictions and most fundamental desires. In the views of many physicians practicing in the United States today and many of their patients, a physician's ability to provide assistance in hastening death is in some cases essential to effective end-of-life medical care.

Oregon's Death With Dignity Act enables patients to seek and willing physicians to provide assistance in dying after compliance with a number of procedural requirements. In providing such assistance, a physician usually prescribes a barbiturate, a Schedule II drug under the regulatory scheme established by the federal Controlled Substances Act. The

Act authorizes a physician licensed under it to prescribe controlled substances listed on Schedules II-V "in the course of professional practice." Accompanying regulations permit licensed physicians to prescribe these substances for any "legitimate medical purpose." These phrases are not defined, so their meanings must be determined by reference to the context in which they are used within the overall statutory scheme. Interpreted in this manner, the terms are plainly intended to draw a distinction between drug-trafficking and patient-centered medical care. Many physicians, scholars of bioethics, and patients alike today consider physician assistance in dying for mentally competent, terminally ill patients, as permitted by Oregon's Death With Dignity Act, to be within the meaning of the statutory and regulatory language of the Controlled Substances Act. In the view of *amici*, such assistance serves a legitimate medical purpose, and is a morally responsible way for the physician to respond to a competent patient's request.

Many physicians consider failure to provide assistance in dying to a patient who requests it to be abandonment of the patient just as death approaches. Continuing to aid a patient in need, indeed never abandoning a patient, is an important and long-standing principle of medical ethics. Depending on the circumstances, providing requested assistance in dying is an appropriate way for a physician to continue to address a patient's needs.

Notwithstanding the views of many in the medical profession and others expert in end-of-life issues, and without any serious effort to learn those views, in 2001 then-Attorney General Ashcroft issued an interpretive rule utilizing the language of the Controlled Substances Act and its accompanying regulations to claim authority to revoke a physician's license to prescribe controlled substances—essential to the practice of medicine—if the physician wrote a prescription pursuant to the Death With Dignity Act. In so doing, At-

torney General Ashcroft reversed the position of his predecessor, Attorney General Janet Reno. The Attorney General's rule is based on a belief that a physician's role is confined to curing or preventing disease or repairing injury. Pet. Brief at 18-19. This reflects a fundamental lack of understanding of contemporary medical practices and ethics.

The authority claimed by the Attorney General would enable him to revoke the licenses of physicians who prescribe controlled substances for other medical uses he considers inappropriate, including many practices currently in nationwide use. Among these are the use, at a dying patient's request, of sufficient controlled substances to relieve pain, even at the risk that the doses required may prove lethal. Another such practice is the use of controlled substances to reduce pain in dying patients who have refused further support from life-sustaining medical technology. An Attorney General who objects to such refusals could sharply curtail them by denying physicians the ability to prescribe controlled substances for relief of pain in patients who have made this choice. The analysis adopted by the Attorney General, if sustained, would empower him to interfere in a wide range of contemporary end-of-life medical practices.

2. The Death With Dignity Act has proved effective, providing comfort to many while not fostering abuse. The Attorney General does not contend otherwise. His claim that the Oregon statute imperils the public health and safety, thereby implicating the Controlled Substances Act, is wholly at odds with the historical record. The Oregon statute furthers rather than threatens the health and safety of the state's citizens.

The statute, as was intended, provides invaluable hope, enhanced palliative care, and relief from anxiety for those stricken with a terminal illness. It also benefits a much larger group of Oregon residents, who are comforted by the knowledge that should their circumstances ever lead them to desire

physician assistance in hastening death, they would be able to obtain it.

Speculation about possible intimidation of patients and abuse of the underprivileged has proved unfounded, according to the clear and reliable record created as a result of the statute's reporting requirements. Patients who seek prescriptions are on average better educated and more affluent than the average Oregonian. Use of hastened death has not spread in a way that might suggest lack of adequate controls; rather, the number of patients seeking prescriptions under the statute has been low—60 in 2004—and generally stable over the seven years the statute has been in effect. About one-third of the patients who obtain lethal prescriptions do not use them, confirming that the statute does not "kill" patients, but rather provides them with assistance in dying only if and when they choose it.

In addition, the statute protects against certain dangers, including underground and unregulated physician assistance in death, and painful acts of self-destruction by patients who feel trapped by their disease and compelled to kill themselves "before it is too late." In these circumstances, the statute serves to extend, not curtail, patients' lives. The Oregon statute is thus a reasonable medical and social response to the difficult end-of-life circumstances faced by some terminally ill patients. It is working as the people of Oregon intended and poses no threat to them.

3. Historically, many aspects of the practice of medicine have been regulated primarily by the states. The Controlled Substances Act allows federal regulation in one and only one limited respect: the prohibition of drug trafficking. This Act was adopted after efforts to control the scourge of drug abuse proved inconsistent and ineffectual in some parts of the country. Even with respect to substances governed by the Controlled Substances Act, however, the act preserves significant authority for the states. Because of the continuing

role of state law, wide variation regarding certain aspects of the use of controlled substances will survive no matter what the outcome of this case.

Indeed, the Controlled Substances Act expressly preserves state authority over controlled substances except in the event of a "direct conflict" with the federal act. Since the writing of a prescription under Oregon's Death with Dignity Act does not constitute drug trafficking and does not violate any express provision of the Controlled Substances Act, there is no "direct conflict" between the federal and state laws. The federal act by its terms does not contemplate, let alone authorize, the extraordinary exercise of federal power that would be required to preclude implementation of Oregon's Death With Dignity Act.

Continuing to permit the writing of prescriptions under Oregon's statute would not, as the Attorney General contends, subordinate his authority to the views of fifty states. Rather, the Attorney General's authority under the Controlled Substances Act is to enforce federal law as far as it goes, which is exclusively to prohibit drug trafficking. Beyond that point, the Act's "express conflict" provision ensures that other issues relating to the use of controlled substances in the "course of professional practice" and for "legitimate medical purpose[s]" remain, appropriately, the province of the states.

ARGUMENT

I. WRITING A PRESCRIPTION PURSUANT TO OREGON'S DEATH WITH DIGNITY ACT IS WITHIN "THE COURSE OF PROFESSIONAL PRACTICE" AND "THE LEGITIMATE PRACTICE OF MEDICINE"

A. Medical Practice Encompasses a Range of Humane Care

The practice of medicine is a morally committed enterprise that encompasses far more than serving as a "mechanic" of

bodily functions. The good physician provides the patient with comprehensive care, addressing the patient's psychological and emotional concerns as well as physical ailments. *Washington v. Glucksberg*, 521 U.S. 702, 779 (2001) (Souter, J., concurring). ("This idea of the physician as serving the whole person is a source of the high value traditionally placed on the medical relationship.")

Thus, the modern physician's role is not confined exclusively to curing or preventing disease or repairing injury. Physicians assist their patients in many different ways, including genetic counseling, dietary care, assistance in reproduction, and various forms of palliative care, including hospice care. Common to all of these forms of modern care are a concern for the alleviation of pain and suffering, emotional as well as physical, and a commitment to the patient's well-being. Various forms of medical assistance aimed at such relief are now taught in medical schools throughout the United States and have gained wide acceptance in the everyday practice of medicine.

Modern views about the range of ways in which physicians should appropriately care for patients have evolved over a period of decades. Palliative and hospice care, for example, were at first controversial, because in providing such care a physician forgoes further efforts at a cure. (Indeed, under the Attorney General's strained and narrow view, such care would not constitute legitimate practice, since it does not involve the prevention or cure of disease. *See* Pet. Brief at 19.) Today, however, a societal consensus has been reached and recognized in law that patients whose prospects for recovery are remote should be able to continue to obtain medical care to relieve their pain and suffering, both physical and emotional. Palliative and hospice care—although at their inception morally controversial—are now nearly universally approved. *See, e.g.*, T. Quill, B. Coombs Lee, and, S. Nunn, *Palliative Treatments of Last Resort: Choosing the Least*

Harmful Alternative, 132 Annals of Internal Medicine 488 (2000) ("Comprehensive palliative care . . . is the standard of care for the dying."); J. Rhymes, *Hospice Care in America*, 264 J. American Med. Ass'n 369 (1990) ("In the 16 years of its existence, hospice care in America has grown from an alternative health care movement to an accepted part of the American health care field.").

Similarly, a patient's right to refuse use of life-sustaining technology has gained acceptance over the past thirty years. Advances in medical knowledge and technology now allow some patients to be kept alive indefinitely, even though they are in a persistent vegetative state from which there is no realistic hope of recovery. Yet many patients do not wish their lives to be prolonged in this way. The law now empowers them to make enforceable declarations of a desire not to be given unwanted life-sustaining care. *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990); *Schiavo v. Schiavo*, No. 05-11628, slip op. at 9-14 (11th Cir. March 25, 2005), *available at* http://www.ca11.uscourts.gov/opinions/ops/200511628.pdf; *In re Quinlan*, 70 N.J. 10, 41 (1976).

For many terminally ill patients, palliative care and the ability to refuse treatment do not adequately address their concerns about their final days. They may face a protracted period of dying, devoid of even the simplest of pleasures, with a loss of functional capacity, possibly unremitting pain and suffering, and long hours of consciousness of the hopelessness of their condition. Many patients find this prospect unbearable. Increasingly, the medical profession and contemporary medical ethics have come to consider it appropriate to offer these patients a humane means of addressing their concerns. For some patients, this permits death with a dignity that they feel would otherwise be "denied . . . by their consciousness of dependency and helplessness as they [approach] death." *Glucksberg*, 521 U.S. at 779 (Souter, J.

concurring). In these circumstances, a physician's providing assistance in dying is not only within the legitimate bounds of medical practice, but a humane and moral response.

It would be more accurate if discussion of this medical practice were framed as "the right to die with dignity," or "hastening death," rather than as "physician-assisted suicide." When a mentally competent patient makes a choice to die during the final stages of a terminal illness there is no "suicide" in any conventional sense. The patient's act is utterly unlike the cutting short, under the influence of depression or mental confusion, of a potentially long and rewarding life. The ingestion of a controlled substance in order to accelerate death may spare the terminally ill patient much suffering, both physical pain and the anguish that, for some, accompanies helplessness and dependence. Reflecting this distinction, the Oregon statute explicitly provides that actions taken pursuant to the statute "shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law." Or. Rev. Stat. 127.880 (2003).

B. Many United States Physicians Today Consider Assistance in Hastening Death To Be Within "the Course of Professional Practice" in Some Cases

The Controlled Substances Act requires that controlled substances be prescribed only "in the course of professional practice." 21 U.S.C. 801-971 (2004) ("CSA" or "the Act") at 21 U.S.C. 802(21). The accompanying regulations contain a similar standard, requiring that any prescription for a controlled substance be for a "legitimate medical purpose." 21 C.F.R. 1306.04(a) (2004). These terms are not defined in either the CSA or its associated regulations and so must be read in their context "with a view to their place in the overall statutory scheme." *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989). *Accord, FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000). The CSA was

intended to prevent drug trafficking and drug abuse, and the terms in question were designed to distinguish the physician who is caring for patients from the physician who is acting as a "pusher," that is a person who is using his license as a physician to make a profit by diverting controlled substances into drug trafficking. *United States v. Moore*, 423 U.S. 122, 142-43 (1975). In determining what conduct constitutes drug-trafficking under the CSA, this Court has distinguished that conduct from "a standard of medical practice generally recognized and accepted in the United States." *Id.* at 139.

Courts have relied on experts to define that standard. As long as the physician is providing care that meets "a standard of medical practice" generally recognized and accepted by the medical community, then the physician's prescribing of controlled substances is permissible under the CSA. *See, e.g., U.S. v. Tran Trong Cuong, M.D.*, 18 F.3d 1132, 1137-39 (4th Cir. 1994) ("[t]he testimony of these witnesses together with that of the government's expert was sufficient to prove the essential elements of the charges"); *United States v. Moore*, 505 F.2d 426 (D.C. Cir. 1974) (MacKinnon, J., dissenting), *reversed, Moore*, 423 U.S. 122 ("[a]s established by expert medical testimony at trial, . . . Dr. Moore's detoxification treatment was not consistent with any method . . . accepted by the medical profession in this country") (internal quotation marks omitted).

A recent survey finds that a majority—57%—of physicians practicing in the United States today consider it ethical to assist a terminally ill, mentally competent patient who has made a considered choice to terminate life in order to avoid unbearable suffering, as the Oregon statute permits. Or. Rev. Stat. 127.800-995 (2003) ("Oregon statute"), *available at* http://www.leg.state.or.us/ors/127.html; Poll conducted by Louis Finkelstein Institute for Social and Religious Research and HCD Research, *Physician-Assisted Suicide Survey*, (March 2005), *available at* http://www.jtsa.edu/research/finkelstein/

surveys/pas.shtml. Other studies have found similar support among a plurality of physicians. K. Novielli, *Correlates of Physicians' Endorsement of the Legalization of Physician-assisted Suicide*, 75 Academic Medicine S53 (2000).

The pages of respected medical journals also demonstrate that a significant number of physicians today consider assistance in dying to be squarely within the bounds of legitimate medical practice, whether the patient's motivation is the alleviation of physical pain or relief from existential suffering. *See, e.g.*, T. Quill and C. Cassel, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138 Annals of Internal Medicine 208 (2003) (summarizing views of physicians and observing that many professional medical organizations do not view assisted suicide or hastening death as inappropriate); T. Quill, B. Lo, and D. Brock, *Palliative Options of Last Resort: A Comparison of Voluntarily Stopping Eating and Drinking, Terminal Sedation, Physician-Assisted Suicide and Voluntary Active Euthanasia*, 278 J. American Med. Ass'n 2099 (1997) (discussing end-of-life options and contending that, in certain circumstances, assistance in hastening death is appropriate medical care); F. Miller, *et al.*, *Regulating Physician-Assisted Death*, 331 N. Eng. J. Med. 119 (1994) (contending that assistance in dying is a medical practice, albeit one reserved for extraordinary circumstances).

The very authorities cited by the Attorney General demonstrate that the unanimity he claims to find among medical professionals does not exist. For example, the Attorney General says that "[n]umerous health care experts have . . . agreed" that physician assistance in hastening death is never a legitimate medical practice, citing the report of the New York State Task Force on Life and the Law, *When Death Is Sought: Assisted Suicide and Euthanasia in the Medical Context* (May 1994) ("New York Task Force Report"). Pet. Brief at 23. The Attorney General fails to mention that although the Task

Force recommended against legalization (principally on the basis of speculative fears that have not been realized in Oregon), the report also made clear that some Task Force members did not "share the conclusion that assisted suicide is inherently unethical or incompatible with medical practice." New York Task Force Report at 140, *available at* http://www.health.state.ny.us/nysdoh/provider/death.htm. "In fact, they believe that in appropriate circumstances, this assistance would manifest a physician's commitment and duty to his or her patient." *Id.*

As important as physicians' stated opinions is their actual practice. While statistics are necessarily elusive since assistance in hastening death is illegal in most states, the evidence available indicates that the practice has existed in secret in the United States for some time. *See, e.g.,* D. E. Meier, *et al., A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 New Eng. J. Med. 1193 (1998) (11% of physicians polled reported that under current legal constraints, there are circumstances in which they would prescribe a medication for a competent patient to use with the primary intention of ending his or her life); L. R. Slome, *et al., Physician-Assisted Suicide and Patients with Human Immunodeficiency Virus Disease*, 336 N. Eng. J. Med. 417 (1997) (53% of 117 Bay area physicians specializing in the care of patients with AIDS indicated that they had acceded at least once to a request to hasten death); E. Emanuel, *et al., Euthanasia and Physician-assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 Lancet 1805 (1996) (in one study, half of oncologists surveyed had received a request for assisted death, and 14% had complied).

In arguing that assistance in hastening death is outside the scope of legitimate medical practice, some point to the Hippocratic Oath, which prohibits the giving of a "deadly drug." Ancient Medicine: Selected Papers of Ludwig Edelstein 6

(Owsei Temkin and C. L. Temkin eds. 1987). Their views are informed more by tradition, however, than by analysis. Moreover, it is a tradition with questionable historical foundations and little viability today. This provision in the Oath, like many of its other provisions, did not reflect accepted medical practice in ancient Greek city-states, where, upon request, a physician would provide a lethal drug for a suffering patient he could not cure. *Id.* at 11-13. More importantly, today the Hippocratic Oath is administered at only one U.S. medical school in its original form; its prohibitions on many practices integral to contemporary medicine have led to its abandonment or replacement at all other U.S. schools. Moreover, only 6 of 122 U.S. medical schools administer an oath that would prohibit physician assistance in hastening death. *See, e.g.,* A. C. Kao and K. P. Parsi, *Content Analyses of Oaths Administered at U. S. Medical Schools in 2000*, 79 Academic Medicine 882 (2004).

The Attorney General's contention that physician assistance in dying is uniformly condemned by the medical profession under all circumstances is demonstrably incorrect. And while admittedly there is some disagreement in the medical and bioethics communities about physician assistance in hastening death, this adduces nothing: many practices about which there is disagreement among professionals are clearly within "the course of professional practice."

The cited polls, the views of physicians and others as expressed in respected medical publications, and reports of actual physician practice demonstrate that assistance in hastening death is accepted by a substantial percentage of physicians and scholars of bioethics as legitimate and humane. Thus, the practice is within "the course of professional practice," and serves a "legitimate medical purpose," as required by the Controlled Substances Act and its accompanying regulations. 21 U.S.C. 802(21); 21 C.F.R. 1306.04 (a). The Attorney General's strained interpretation of this language,

which leads him to conclude that prescribing a controlled substance to provide a patient with the means of hastening death can *never* constitute a legitimate medical practice, ignores this solid evidence.

C. Many Competent Patients Consider Physician Assistance in Hastening Death to be Within the Range of Care They Should Be Able to Obtain from Their Physicians

Coinciding with the evolution of modern medical practice has been increased respect by physicians for the patient's autonomy. Modern medical practice requires a physician to listen carefully to the patient's needs and desires and be skilled in imparting to the patient the medical options available. No longer do patients simply accept a treatment prescribed by their doctors, but instead they participate, based on their doctors' advice about medical consequences, in selecting, planning, and conducting their own medical care, and ultimately in assuming responsibility for implementing it. This development has been particularly pronounced with respect to end-of-life care.

Thirty years ago, before the seminal decision in *Quinlan*, there was no generally recognized legal right to refuse or direct the withdrawal of life-sustaining treatment. *See Cruzan*, 497 U.S. at 270; *Quinlan*, 70 N.J. at 41. No established public policy set the contours of the decision-making rights of seriously ill or injured patients. The physicians participating in *Quinlan* maintained that such judgments are exclusively medical in nature and that withdrawal of life-sustaining treatment violated accepted ethical standards. *Quinlan* reshaped the law, medicine, and medical ethics with its holding that the patient's judgment must prevail over the physician's with respect to certain decisions at the end of the patient's life.

By providing a legal means of realizing an option long sought and sometimes obtained in the shadows by the terminally ill, the Oregon statute reflects this increased respect for patient autonomy. For some patients, given their symptoms, the imminence of their death, its likely form, and their most deeply held values and convictions, the prospect of survival in a wholly dependent or vegetative state or in unbearable and unrelievable physical pain or suffering is, literally, worse than death. For them, a physician's dispensing of a controlled substance to make their death tolerable constitutes fulfillment of the physician's moral duty to attend to their needs.

The percentage of potential patients and their families who consider assistance in dying appropriate for the terminally ill who desire it now constitutes a sizeable majority. In 2003, members of the public were asked, "When a person has a disease that cannot be cured, do you think physicians should be allowed to end that patient's life by some painless means, if the patient requests it?" Seventy-two percent of those polled answered "Yes." K. Jost, *Right to Die*, 15 CQ Researcher No. 18 at 428 (2005), *citing* polls by Public Agenda and Gallup Organization conducted in January 1950 and May 2003.[2]

It is inaccurate to dismiss patients who desire assistance in dying as merely suffering from depression. As Justice Souter wrote in his concurrence in *Glucksberg*,

> The patients here sought not only an end to pain (which they might have had, although perhaps at the price of stupor) but an end to their short remaining lives with a dignity that they believed would be denied them by powerful pain medication . . . . In that period when the end is imminent, they said, the decision to end life is closest to decisions that are generally accepted as proper instances of exercising autonomy over one's own

[2] Notably, the survey question describes a process in which, in sharp contrast to the more restrictive Oregon law, the physician may administer a lethal dose of a controlled substance. Under Oregon law, the patient must ingest the substance.

body, . . . instances in which the help of physicians is accepted as falling within the traditional norm.

Glucksberg, 521 U.S. at 779. *See also Glucksberg*, 521 U.S. at 742 (Stevens, J., concurring) (noting the terminally ill patient's "basic interest in controlling the manner and timing of her death").

II. OREGON'S DEATH WITH DIGNITY ACT DOES NOT THREATEN THE PUBLIC HEALTH AND SAFETY

A. There is No Evidence that the Oregon Statute Has Harmed the Public Health and Safety

The Oregon statute was adopted by direct vote of the people of the state in 1994 and again in 1997. Or. Rev. Stat. 127.800 *et seq.* (2003). It has now been in effect for more than seven years, and because of its reporting requirements, detailed information is now available about its implementation. Or. Rev. Stat. 127.855 (2003). The evidence is uniformly favorable. Or. Dep't of Human Services, Seventh Annual Report on Oregon's Death With Dignity Act (2005), *available at* http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf ("2004 Report"). Speculative fears about abuse have not materialized, the expected benefits have been achieved, and unanticipated advantages have been realized as well. There is no evidentiary basis for invoking the Controlled Substances Act, 21 U.S.C. 801-971, as the Attorney General seeks to do, on the grounds that the Death With Dignity Act imperils the public health and safety of the people of Oregon. *See* Memorandum for the Attorney General from Office of Legal Counsel, Department of Justice (June 27, 2001), Pet. App. 106a. ("OLC Memorandum").

Importantly, there is no evidence that any patient has died other than in accordance with his or her own wishes. Notably, many patients who obtain a prescription for a lethal dose of a controlled substance choose never to ingest it. In 2004

one-fifth of the 60 patients who obtained prescriptions died from natural causes, and another one-fifth were still alive at year's end. 2004 Report at 12. Moreover, many patients seriously consider obtaining a prescription for a lethal dose but then never choose to do so. 2004 Report at 16. Under the statute, mentally competent, terminally ill patients remain securely in control of decision-making about their lives.

Initial concern that the statute's restrictions might be loosened in practice has not proved warranted. Use of the statute has been limited, and levels of use have remained stable. Only 208 people in the last seven years have obtained assistance in dying. The 37 deaths attributable to hastened death in 2004 amount to about one in 800 deaths among Oregonians. 2004 Report at 16. Nor has hastened death been used primarily by individuals who might be thought vulnerable to intimidation or abuse. Those choosing assisted death had on average a higher level of education and better medical coverage than terminally ill Oregonians who did not obtain assistance in dying. 2004 Report, Tables 2 and 4. The elderly, women, people with disabilities, and members of disadvantaged racial minorities have not been disproportionately affected. Only 3% of those who obtained assistance in dying were reported to have expressed concern about the financial costs of treatment. 2004 Report, Table 4. There is no evidence of influence by greedy relatives, callous physicians, or profit-minded health insurers. In short, there is no evidence that the Death With Dignity Act has been a dangerous policy choice. To the contrary, it has facilitated autonomous decision-making by mentally competent, terminally ill patients at a time when they have little other control over their lives.

B. The Oregon Statute Has Provided the Benefits Expected by Oregon Voters

This favorable record is in part the result of the procedural protections imposed by the Oregon statute. In order for a

prescription for a lethal dose to be written: (1) the patient must be a capable adult resident of Oregon diagnosed with a terminal illness that will likely lead to death within six months, Or. Rev. Stat. 127.800(12), 127.805 (2003); (2) the patient must make two oral requests, separated by at least fifteen days, *id*. at 127.840, and one written request, signed in the presence of two witnesses, *id*. at 127.810; (3) the prescribing physician and a consulting physician must confirm the terminal diagnosis and prognosis and determine that the patient is capable, *id*. at 127.815(1)(a), 127.820; (4) the prescribing physician must inform the patient of feasible alternatives to hastened death, including comfort care, hospice care, and pain control, *id.* at 127.815(1)(c)(E); (5) satisfaction of the foregoing requirements and a report of relevant data must be entered on the patient's medical record, *id.* at 127.855; and (6) the prescribing physician must request (but may not require) that the patient notify his or her next of kin of the prescription request. *Id.* 127.835. If either the prescribing or the consulting physician believes that the patient lacks the capacity to make a rational choice, the patient must be referred for counseling. *Id.* at 127.825. The statute protects physicians from criminal liability only if they have complied with all of its requirements. *Id*. at 127.890 (4).

Almost all in Oregon who have sought prescriptions under the Death With Dignity Act cited emotional suffering arising from the loss of control over the circumstances of their lives as a major reason for their decision. 2004 Report, Table 4. Others sought to avoid loss of physical capacity or of their sense of dignity. *Id*. Some feared intolerable pain not controllable by medication. *Id*. All of these concerns must be acknowledged as serious and deeply felt. *See Cruzan*, 497 U.S. at 292 (1990) (Scalia, J., concurring) (noting "the constantly increasing power of science to keep the human body alive for longer than any reasonable person would want to inhabit it"). For these Oregon residents, the Death With Dignity Act affords a final measure of self-determination that

their illnesses might otherwise have denied them. It enables them to end their lives in a manner they consider humane and dignified. Or. Rev. Stat. 127.805 (2003).

At the same time, the statute comforts many who never seek to utilize it, but might have done so in different circumstances. It provides all of the citizens of Oregon with the knowledge that should a terminal illness place them in a condition they find intolerable, an escape would be available.

C. The Oregon Statute Has Also Brought Unexpected Benefits

The Death With Dignity Act has produced unexpected benefits as well. In a survey of Oregon physicians concerning their attitudes toward and experiences with end-of-life care since passage of the statute, more than 75% of physicians interviewed reported that "they had made efforts to improve their knowledge of the use of pain medications in the terminally ill" and "their confidence in the prescribing of pain medications had improved." L. Ganzini, *et al., Oregon Physicians' Attitudes About and Experiences With End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 J. American Med. Ass'n 2363, 2365-66 (2001). Almost 70% of physicians also "reported that they sought to improve their recognition of psychiatric disorders, such as depression." *Id*. at 2365. Finally, referrals to hospice care have increased dramatically since passage of the statute. M. McCauley, *Taking a Look at 2004* at 2, Table: Hospice Penetration Rates, (Or. Hospice Ass'n Newsletter 2005) *available at* http://www.oregonhospice.org/graphics/pdfs/2004newsletter0305.pdf (showing that hospice usage in Oregon nearly doubled from 1994 to 2003 and is well above the national average). The Oregon statute produces these results by focusing attention on the physical and mental suffering that accompanies terminal illness and thus by encouraging efforts to better alleviate these burdens.

D. Dangers That Exist Elsewhere Are Avoided in Oregon

While only a small number of terminally ill patients formally request a lethal prescription and even fewer ultimately ingest one, studies show that many more terminally ill patients seriously consider seeking assistance in dying. E. Emmanuel, *et al.*, *Attitudes and Desires Related to Euthanasia and Physician-assisted Suicide Among Terminally Ill Patients and Their Caregivers*, 284 J. American Med. Ass'n 2460-68 (2000). Those who lack the legal option to seek assistance in dying may seek assistance illegally, without the safeguards the Oregon statute affords that state's residents. Other such patients will resort to violent self-help. The Oregon statute regulates assistance in dying and subjects it to scrutiny through extensive record-keeping requirements.

The Controlled Substances Act provides that the public health and safety is one factor for the Attorney General to consider in determining whether registration of a particular physician is consistent with the public interest. 21 U.S.C. 823(a)(6). The evidence establishes that the Death With Dignity Act has promoted, not harmed, the health and safety of Oregon residents.

III. THE CONTROLLED SUBSTANCES ACT APPROPRIATELY PRESERVES STATE AUTHORITY OVER MANY ASPECTS OF MEDICAL PRACTICE, INCLUDING THE USE OF CONTROLLED SUBSTANCES IN MEDICAL TREATMENT AT THE END OF LIFE

A. The Controlled Substances Act Aims to Curb Drug Trafficking, Preserving State Authority Except in Cases of a "Direct Conflict" with the Federal Act

States have traditionally held primary responsibility for many aspects of the regulation of medical care. *See, e.g,*

Bowen v. American Hosp. Ass'n, 476 U.S. 610, 645 (1986) (regarding proposed federal regulations governing medical care of newborns, "[t]he propriety of the exertion of . . . [federal] authority must be tested by its relation to the purpose of the [statutory] grant and with suitable regard to the principle that whenever the federal power is exerted within what would otherwise be the domain of state power, the justification of the exercise of the federal power must clearly appear"). When some states proved less than effective in deterring drug trafficking, however, Congress stepped in and, by enactment of the Controlled Substances Act, sought to augment with federal support existing state efforts to keep drugs out of illicit channels of distribution. At the time it passed the federal act, Congress confronted a mosaic of existing state provisions and practices relating to these drugs. It decided to leave most of that state structure in place, 21 U.S.C. 903, and to enhance, not replace, state law. Consistent with its limited goals, Congress expressly limited the new authority it extended to the federal government by recognizing and approving the states' continuing role. *Id.*

That the CSA was intended and designed to deter drug trafficking has been recognized by this Court and others. *See, e.g., Moore*, 423 U.S. at 139; *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975). In *Moore*, the Court interpreted the statutory language, "in the course of professional practice," and distinguished between a physician who dispensed drugs "within . . . legitimate channels" and one who "sold drugs, not for legitimate purposes, but primarily for the profits to be derived therefrom." *Moore,* 423 U.S. at 135, *citing* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4575 (internal quotations marks omitted). Medical practice under the Death With Dignity Act does not involve trafficking or the distribution of drugs "primarily for . . . profit[]." *Id.*

The Attorney General relies on the statutory and regulatory provisions that permit him to revoke a physician's license to

prescribe controlled substances if the physician has prescribed such substances for a reason other than "in the course of professional practice" or for other than a "legitimate medical purpose." 21 U.S.C. 802(21); C.F.R. 1306.04. Since without such prescription-writing authority a physician as a practical matter cannot practice medicine, and since controlled substances, particularly barbiturates, are what physicians find medically responsible to provide to patients who choose to hasten death, 2004 Report at 14, the Attorney General's interpretive rule would effectively nullify the Oregon law. Interpretive Rule, AG Order No. 2534-2001 (Nov. 9, 2001), Pet. App. 100a. Yet the CSA provides that:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a *positive conflict* between that provision of this sub-chapter and that State law so that the two cannot consistently stand together.

21 U.S.C. 903 (emphasis added).

The CSA, which addresses the diversion of drugs into illicit channels of distribution, does not by its terms prohibit the use of controlled substances in the hastening of death. The Death With Dignity Act does not by its terms authorize or foster any form of drug trafficking. The two statutes can stand together without tension, much less conflict. Congress provided that the CSA should be interpreted to avoid unnecessary collision with state law. In clear violation of this provision, the Attorney General has contrived a results-driven analysis that seeks to create a conflict where none exists. His interpretive rule is in direct contravention of the "positive conflict" provision of the CSA.

B. Significant Aspects of the Medical Use of Controlled Substances Have Remained Free of Federal Control

The CSA's express deference to state regulation of aspects of medical practice is reflected in several ways. For example, once the Attorney General or his surrogate has identified at least one legitimate medical use of a substance, a physician is free to prescribe the substance for any medical purpose. *See* J. Beck & E. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug Law Journal 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.").

In addition, the continuing role of the states results in considerable diversity. While no state purports to authorize conduct that would violate federal law, at least 36 states have exercised authority over important aspects of the use of controlled substances in patient care by enacting statutes or issuing regulations or guidelines. Some states encourage pain management. *See, e.g.*, Or. Rev. Stat. 677.474 (2003), *available at* http://www.leg.state.or.us/ors/677.html ("Notwithstanding any other provision of this chapter, a physician licensed under this chapter may prescribe or administer controlled substances to a person in the course of the physician's treatment of that person for a diagnosed condition causing intractable pain."). Other states have adopted model guidelines issued in 1998 by the Federation of State Medical Boards of the United States that are more restrictive, at least in tone. *See, e.g.*, Nev. Admin. Code 630.187 (2004), *available at* http://www.leg.state.nv.us/NAC/NAC-630.html#NAC630Sec187, adopting *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, available at* http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/model_pain_guidelines.htm ("the physician

should adjust drug therapy to the individual medical needs of each patient"). Other states specifically address end-of-life care and expressly authorize the physician to consider the patient's personal dignity as well as comfort. *See, e.g.*, Me. R. 02-373-011, § 3 ("The Principles of End of Life Pain Therapy: In the instance of chronic end of life pain, a treatment plan which addresses the goals of comfort and personal dignity, developed at the time of original diagnosis, is sufficient. . . ."), *available at* ftp://ftp.maine.gov/pub/sos/cec/rcn/apa/02/373/373c011.doc. *See generally*, St. Louis University and American Society of Law, Medicine & Ethics, State Pain Policies [and] Regulations, *available at* http://www.painandthelaw.org/statutes/painpolicy_regulations.php.

Moreover, many but not all states have adopted prescription monitoring programs to deter illegal diversion. There is variation in the drugs covered and the type of monitoring utilized. *See, e.g.*, D. Joranson, *et al., Pain Management and Prescription Monitoring*, 23 J. Pain and Symptom Management 231, 233, Table 1, States with Prescription Monitoring Programs (2002) ("[i]n practice, [these programs] take different forms because each state government determines the goals, structure, and organization of its program.").

These differences in the regulation and prescribing of controlled substances would be inexplicable were the Attorney General, as he claims, in fact directed by the Controlled Substances Act to administer "uniform" regulation of controlled substances. See Pet. Brief at 14. The variation in state laws and physician practices that the Attorney General considers inappropriate is well-entrenched and will remain so regardless of the outcome of this case.

C. The Attorney General Could Apply His Interpretation to Interfere with Many Other Forms of End-of-Life Medical Care, Including Palliative Care and Refusals of Treatment

The analysis advanced by the Attorney General has implications far beyond the hastening of death under Oregon's Death With Dignity Act. Were the Attorney General's interpretation of his authority under the statutory scheme upheld, there would be nothing to prevent him from asserting federal control over all uses of controlled substances in medicine, including in connection with what are now common medical practices across the country. Although the Attorney General currently distinguishes practice under the Oregon statute from other medical uses of controlled substances, Interpretive Rule § 2, Pet. App. at 103a; Pet. Brief at 20 n.7, nothing in the legal analysis he advances provides a basis for drawing a clear line between practice under the Oregon statute and other uses of controlled substances in end-of-life medical care.

For example, many states now, by statute, permit doctors to prescribe sedation sufficient to ensure that a terminally ill patient does not feel pain or experience suffering, even if there is a risk that enough medication to quell the pain or suffering will also be lethal. *See, e.g.*, R.I. Gen. Laws Tit. 5, 5-37.4, *available at* http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.4/INDEX.HTM. The expansive powers claimed by the Attorney General would permit him to conclude that such uses of controlled substances are outside of "the course of professional practice" or do not serve a "legitimate medical purpose," effectively nullifying all of these state laws by federal, executive fiat. The democratic choices of each state's voters could be overridden.

Controlled substances are also commonly prescribed to relieve pain in terminally ill patients who have chosen to refuse further life-sustaining care. If the Attorney General opposes such a patient's right to refuse care, as his filing in

the *Schiavo* case suggests, *Schiavo v. Schiavo*, No. 8:05-CV-530-T-27TBM, Statement of Interest of the United States, March 21, 2005 (M.D. Fla.), *available at* http://news.findlaw.com/hdocs/docs/schiavo/32105dojstmnt.pdf, he could effectively prevent the exercise of this right by threatening to revoke the license of any physician prescribing controlled substances to ease the pain of a patient who rejects further life-sustaining support. His view that the CSA authorizes him to create and implement uniform national rules reflecting what he considers to be "legitimate" medical uses of such substances would permit him to take this step even though the right of a competent, terminally ill patient to refuse such care is now well-established in the law and in medical ethics. Just as the Attorney General argues here that he is not interfering with the right of Oregon physicians to assist in hastening death, but is merely prohibiting the use of controlled substances for this purpose, he could similarly claim that he was not interfering in the right to refuse life-sustaining care, but only limiting the use of controlled substances in connection with it. The *Schiavo* case demonstrates that such concerns are not purely theoretical.

The federal act does not contemplate, much less authorize, administrative rulings by the Attorney General to curtail medical practices that do not conform to his views about how physicians should care for their patients. If the Court were to uphold the Attorney General's rule, however, this could occur. The CSA was not intended to subordinate medical practice to ideology.

D. The Interpretive Rule Also Intrudes on Other State Authority

The Attorney General's interpretive rule encroaches on traditional state authority in another respect: state law has traditionally governed the legality of a person's taking of his own life. Moreover, this issue is most appropriately governed

by legislation, not by executive or judicial order. As forcefully described by Justice Scalia in *Cruzan*:

> [T]he point at which life becomes "worthless," and the point at which the means necessary to preserve it become "extraordinary" or "inappropriate," are neither set forth in the Constitution nor known to the nine Justices of this Court any better than they are known to nine people picked at random from the Kansas City telephone directory; and hence, that even when it is demonstrated by clear and convincing evidence that a patient no longer wishes certain measures to be taken to preserve his or her life, it is up to the citizens of [the state] . . . to decide, through their elected representatives, whether that wish will be honored. It is quite impossible (because the Constitution says nothing about the matter) that those citizens will decide upon a line less lawful than the one we would choose; and it is unlikely (because we know no more about "life and death" than they do) that they will decide upon a line less reasonable.

497 U.S. at 293. Justice Scalia added that the view that government should not prohibit its citizens from ever choosing to end life is one "our States are free to adopt if they wish." *Id.* at 300.

The Attorney General's interpretive rule usurps this power from the states and from the voters of Oregon. It replaces their democratic choice about the range of options to be available for one of life's most intensely personal and important decisions with the preferences of a federal executive, unsupported by any formal administrative process.

Popular concern about end-of-life issues continues to grow. In the past three years, bills to legalize physician-assisted dying have been introduced in the legislatures of Arizona, California, Hawaii, Vermont, Wisconsin, and Wyoming. H.R. 2313, 47th Leg., 1st Reg. Sess. (Ariz. 2005), *available at* http://www.azleg.state.az.us/Format Document.asp?inDoc

=/legtext/47leg/1r/bills/hb2313p%2Ehtm&DocType=B;Assemb. 654, 2005-06 Reg. Sess. (Cal. 2005), *available at* http://info.sen.ca.gov/pub/bill/asm/ab_0651-0700/ab_654_bill_20050526_amended_asm.pdf; H.R. 1454, 23rd Legis. (Haw. 2005), *available at* http://www.capitol.hawaii.gov/session current/bills/ hb1454_.htm; H.R. 168, 68th Biennial Sess. (Vt. 2005), *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/bills/intro/H-168.HTM; Assemb. 348, 96th Leg. Sess., 2003-04 Reg. Sess. (Wis. 2003), *available at* http://www.legis.state.wi.us/2003/ data/AB-348.pdf; S. 7, 57th Leg., 2004 Budget Sess. (Wy. 2004), *available at http://legisweb.state.wy.us/2004 /introduced/SF007.pdf.* The Attorney General's interpretive rule would close the door to ongoing efforts in the "laboratory of the states" to address difficult issues at end of life through careful legal reform. *Glucksberg*, 521 U.S. at 737 (O'Connor, J. concurring).

The people of Oregon have made a reasonable policy choice that has worked as they intended. The Oregon statute authorizes medical care that is well within the legitimate practice of medicine as understood by many physicians, scholars of bioethics, and patients today. It does not conflict in any way with federal efforts to thwart drug trafficking, and is a legitimate exercise of state legislative power. This Court should not permit the Attorney General to block access by terminally ill Oregon patients to medications they request, that their physicians find appropriate, and that the people of Oregon have authorized them to obtain.

CONCLUSION

This Court should affirm the decision below.

Respectfully submitted.

RONALD A. LINDSAY
SEYFARTH SHAW LLP
815 Connecticut Ave., N.W.
Suite 500
Washington, D.C. 20006
(202) 463-2400

REBECCA P. DICK *
DAVID SONTAG
DECHERT LLP
1775 Eye St., N.W.
Washington, D.C. 20006
(202) 261-3500

* Counsel of Record

APPENDIX

APPENDIX

SIGNATORIES

Margaret P. Battin, M.F.A., Ph.D.
Distinguished Professor
Department of Philosophy
Adjunct Professor of Internal Medicine
Division of Medical Ethics
University of Utah
260 S. Central Campus Dr.
Orson Spencer Hall, Room 341
Salt Lake City, Utah

Tom L. Beauchamp, Ph.D.
Professor of Philosophy
Senior Research Scholar, Kennedy Institute of Ethics
Georgetown University
Washington, D.C.

Dan W. Brock, Ph.D.
Frances Glessner Lee Professor of Medical Ethics
Director, Division of Medical Ethics
Department of Social Medicine
Harvard Medical School
641 Huntington Avenue,
4th Floor
Boston, Massachusetts

Edward Lowenstein, M.D.
Henry Isaiah Dorr Professor of Anaesthesia
Professor of Medical Ethics
Harvard Medical School
Boston, Massachusetts

Provost
Department of Anesthesia and Critical Care
Massachusetts General Hospital
Boston, Massachusetts

S. James Adelstein, M.D., Ph.D.
Paul C. Cabot Distinguished Professor of Medical Biophysics
Department of Pathology
Harvard Medical School
260 Longwood Avenue
Boston, Massachusetts

Anita L. Allen-Castellitto, Ph.D., J.D.
Henry R. Silverman Professor of Law, Professor of Philosophy, and Senior Fellow, Department of Bioethics
University of Pennsylvania
3400 Chestnut Street
Philadelphia, Pennsylvania

Dr. Marcia Angell, M.D.
Senior Lecturer
Department of Social Medicine
Harvard Medical School
641 Huntington Avenue
Boston, Massachusetts

Robert Arnold, M.D.
Leo H. Criep Chair in Patient Care
Director, Institute for Doctor-Patient Communication
University of Pittsburgh School of Medicine
200 Lothrop Street
Pittsburgh, Pennsylvania

John D. Arras, Ph.D.
Porterfield Professor of Biomedical Ethics
Professor of Philosophy
University of Virginia
P.O. Box 400780
512 Cabell Hall
Charlottesville, Virginia

Charles H. Baron, A.B., Ph.D., LL.B.
Professor of Law
Boston College Law School
885 Centre Street
Newton Centre, Massachusetts

Howard Brody, M.D., Ph.D.
University Distinguished Professor
Family Practice, Philosophy, and Center for Ethics and Humanities in the Life Sciences
Michigan State University
East Lansing, Michigan

Robert V. Brody, M.D.
Clinical Professor of Medicine and Family & Community Medicine
University of California at San Francisco
San Francisco, California
Chair, Ethics Committee and Chief, Pain Consultation Clinic
San Francisco General Hospital
San Francisco, California

Allen Buchanan, Ph.D.
James B. Duke Professor of Philosophy and Public Policy
Duke University
Durham, North Carolina

Norman L. Cantor, J.D.
Professor of Law
Justice Nathan Jacobs Scholar
Rutgers Law School
123 Washington St.
Newark, New Jersey

Arthur L. Caplan, Ph.D.
Emmanuel and Robert Hart Professor of Bioethics
Chair, Department of Medical Ethics
Director, Center for Bioethics
University of Pennsylvania
3401 Market Street, Suite 320
Philadelphia, Pennsylvania

Christine K. Cassel, M.D.
President
American Board of Internal Medicine
510 Walnut Street, Suite 1700
Philadelphia, Pennsylvania

Eric J. Cassell, M.A., M.D., M.A.C.P.
Clinical Professor of Public Health Weill Medical College of Cornell University
New York, New York

Adjunct Professor of Medicine
McGill University Faculty of Medicine
Montreal, Quebec, Canada

R. Alta Charo, J.D.
Elisabeth S. Wilson Professor of Law and Bioethics
University of Wisconsin Law and Medical Schools
Associate Dean for Research and Faculty Development
University of Wisconsin Law School
5211C Law Building
975 Bascom Hall
Madison, Wisconsin

Robert Cook-Deegan, M.D.
Director, Center for Genome Ethics, Law & Policy
Duke Institute for Genome Sciences & Policy
Research Professor of Public Policy Studies
Research Professor of Medicine
Duke University
Box 90141
Durham, North Carolina

Norman Daniels, Ph.D.
Mary B. Saltonstall Professor
Professor of Ethics and Population Health
Department of Population and International Health
Harvard School of Public Health
Building I, Room 1104C
665 Huntington Avenue
Boston, Massachusetts

Nancy Neveloff Dubler, LL.B.
Director, Division of Bioethics
Department of Epidemiology and Population Health
Montefiore Medical Center
111 East 210th Street
Bronx, New York

Professor of Bioethics
Albert Einstein College of Medicine
Yeshiva University
Bronx, New York

Ronald Dworkin, M.A., LL.B.
Frank Henry Sommer Professor of Law and of Philosophy
New York University
Vanderbilt Hall
40 Washington Square South
Room 411-I
New York, New York

Jeremy Bentham Professor of Jurisprudence
University College
London, England

Ruth Faden, Ph.D., M.P.H.
Philip Franklin Wagley Professor of Biomedical Ethics
Director
The Phoebe R. Berman Bioethics Institute
Johns Hopkins University
Baltimore, Maryland

Daniel D. Federman, M.D.
Carl W. Walter Distinguished Professor of Medicine
Senior Dean for Alumni Relations and Clinical Teaching
Harvard Medical School
Gordon Hall
25 Shattuck Street
Boston, Massachusetts

Joel E. Frader, M.D., M.A.
Professor of Pediatrics
Professor of Medical Humanities and Bioethics
Feinberg School of Medicine
Northwestern University
Evanston, Illinois

Division Head, General Academic Pediatrics
Children's Memorial Hospital
2300 Children's Plaza, #16
Chicago, Illinois

Leslie Pickering Francis, Ph.D., J.D.
Alfred C. Emery Professor of Law
Professor and Chair
Department of Philosophy
University of Utah
Salt Lake City, Utah

John M. Freeman, M.D.
Lederer Professor of Pediatric Epilepsy
Professor of Neurology and Pediatrics
Johns Hopkins Medical Institutions
Baltimore, Maryland

Bernard Gert, Ph.D.
Stone Professor of Intellectual and Moral Philosophy
Department of Philosophy
Dartmouth College
6035 Thornton Hall
Hanover, New Hampshire

Samuel Gorovitz, Ph.D.
Professor of Philosophy
The College of Arts and Sciences
Founding Director
Renée Crown University Honors Program
Syracuse University
Syracuse, New York

Jeffrey Kahn, Ph.D., M.P.H.
Maas Family Chair in Bioethics
Director, Center for Bioethics
University of Minnesota
N504 Boynton
410 Church St., SE
Minneapolis, Minnesota

Yale Kamisar, J.D.
Professor of Law
University of San Diego School of Law
San Diego, California

Clarence Darrow Distinguished University Professor Emeritus of Law
University of Michigan Law School
Ann Arbor, Michigan

Jerome P. Kassirer, M.D.
Distinguished Professor
Tufts University School of Medicine
136 Harrison Ave.
Boston, Massachusetts

Professor (Adjunct) of Medicine and Bioethics
Case Western Reserve University
Cleveland, Ohio

Editor-in-Chief Emeritus
New England Journal of Medicine
Boston, Massachusetts

Sylvia Law, J.D.
Elizabeth K. Dollard Professor of Law, Medicine, and Psychiatry
New York University Law School
Vanderbilt Hall
Room 429
New York, New York

Robert S. Lawrence, M.D.
Edyth H. Schoenrich Professor of Preventive Medicine
Associate Dean for Professional Practice and Programs
Director, Center for a Livable Future
Bloomberg School of Public Health
Johns Hopkins University
615 N. Wolfe St.
Baltimore, Maryland

Robert J. Levine, M.D.
Co-chair of the Executive Committee
Yale University Interdisciplinary Project in Bioethics
Director
Law, Policy and Ethics Core
Center for Interdisciplinary Research on AIDS
Professor of Medicine and Lecturer in Pharmacology
Yale University
New Haven, Connecticut

Charles F. McKhann, M.D.
Professor Emeritus
Section of Oncology
Department of Surgery
Yale University School of Medicine
New Haven, Connecticut

Alan Meisel, J.D.
Professor of Law and and Dickie, McCamey & Chilcote Professor of Bioethics
Director, Center for Bioethics and Health Law
University of Pittsburgh School of Law
Pittsburgh, Pennsylvania

David Orentlicher, M.D., J.D.
Samuel R. Rosen Professor of Law
Co-Director, Center for Law and Health
Indiana University School of Law-Indianapolis Core Faculty
Indiana University Center for Bioethics
Adjunct Professor of Medicine
Indiana University School of Medicine
530 W. New York Street
Indianapolis, Indiana

Timothy E. Quill, M.D.
Professor of Medicine, Psychiatry and Medical Humanities
Director, Center for Palliative Care and Clinical Ethics
University of Rochester School of Medicine
Box 601
601 Elmwood Avenue
Rochester, New York

Arnold S. Relman, M.D.
Professor Emeritus of Medicine and Social Medicine
Harvard Medical School
Boston, Massachusetts

Ben A. Rich, J.D., Ph.D.
Associate Professor of Bioethics
University of California, Davis School of Medicine
Sacramento, California

John A. Robertson, J.D.
Vinson and Elkins Chair
University of Texas School of Law
727 East Dean Keeton Street
Austin, Texas

Thomas M. Scanlon, Ph.D.
Alford Professor of Natural Religion, Moral Philosophy, and Civil Polity
Department of Philosophy
Harvard University
208 Cambridge Hall
Cambridge, Massachusetts

Lawrence J. Schneiderman, M.D.
Department of Family & Preventive Medicine
Department of Medicine
School of Medicine
University of California, San Diego
San Diego
San Diego, California

Anita Silvers, Ph.D.
Professor
Department of Philosophy
San Francisco State University
1600 Holloway Avenue
San Francisco, California

Peter Singer, B. Phil.
Ira W. DeCamp Professor of Bioethics
University Center for Human Values
Princeton University
Princeton, New Jersey

Bonnie Steinbock, Ph.D.
Professor
Department of Philosophy
University at Albany/State University of New York
Albany, New York

Jeremy Sugarman, M.D., M.P.H., M.A.
Harvey M. Meyerhoff Professor of Bioethics and Medicine
Phoebe R. Berman Bioethics Institute and Department of Medicine
Johns Hopkins University
Hampton House 351
624 N. Broadway
Baltimore, Maryland

Judith J. Thomson, Ph.D.
Professor of Philosophy
Department of Linguistics and Philosophy
Massachusetts Institute of Technology
Cambridge, Massachusetts

Robert D. Truog, M.D.
Professor of Medical Ethics and Anaesthesia
Department of Social Medicine
Division of Medical Ethics
Harvard Medical School
641 Huntington Avenue
Boston, Massachusetts

Sidney H. Wanzer, M.D.
Board of Directors
End-of-Life Choices of Greater Boston
333 Thoreau Street
Concord, Massachusetts

Richard A. Wasserstrom, Ph.D., LL.B.
Professor Emeritus
Department of Philosophy
University of California
Santa Cruz
Santa Cruz, California

William J. Winslade, Ph.D., J.D.
Institute for the Medical Humanities
Old Red, Suite 2.210
University of Texas Medical Branch
301 University Boulevard
Galveston, Texas

Peter M. Winter, M.D.
Professor Emeritus
Department of Anesthesiology
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania

AMICUS CURIAE

BRIEF

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Supreme Court of the United States

ALBERTO R. GONZALES, ET AL., PETITIONERS

v.

STATE OF OREGON, ET AL., RESPONDENTS.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* OF A COALITION OF MEDICAL ASSOCIATIONS AND SOCIETIES; PAIN, PALLIATIVE, AND ELDER CARE ASSOCIATIONS; AND DISTINGUISHED INDIVIDUAL PAIN, PALLIATIVE, AND ELDER CARE PROFESSIONALS IN SUPPORT OF RESPONDENTS

ANAND AGNESHWAR
VIJAY BALIGA
ARNOLD & PORTER LLP
399 Park Avenue
New York, New York 10022
(212)715-1000

GEOFFREY J. MICHAEL
Counsel of Record
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
(202)942-5000

Attorneys for Amici Curiae

TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

INTERESTS OF *AMICI CURIAE* 1

SUMMARY OF THE ARGUMENT 7

ARGUMENT 7

I. THE TEXT OF THE CSA DOES NOT CONFLICT WITH THE ODWDA 8

II. WELL-ENTRENCHED PRINCIPLES OF FEDERALISM PRECLUDE INTERPRETING THE CSA TO PERMIT THE AG'S INTRUSION INTO AN AREA TRADITIONALLY RESERVED TO THE STATES 12

A. THE REGULATION OF MEDICINE IS A TRADITIONAL STATE FUNCTION 14

B. THE DIRECTIVE IMPEDES THE EXERCISE OF THIS TRADITIONAL STATE FUNCTION AND THWARTS THE ABILITY OF THE STATES TO ACT AS LABORATORIES OF DEMOCRACY 19

C. THE DIRECTIVE DIMINISHES DISCOURSE ON THE ETHICAL

AND PRACTICAL
IMPLICATIONS OF
PHYSICIAN-ASSISTED
SUICIDE 24

III. THE DIRECTIVE WILL INTERFERE WITH PAIN MANAGEMENT DECISIONS 25

CONCLUSION 30

TABLE OF AUTHORITIES

CASES

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 16

Chevron U.S.A. Corp. v. Nat'l Res. Def. Council, Inc.,
467 U.S. 837 (1984) 12

Chisom v. Roemer,
501 U.S. 380 (1991) 1

Conant v. McCaffrey,
172 F.R.D. 681 (N.D. Cal. 1997) 18

Conant v. Walters,
309 F.3d 629 (9th Cir. 2002) 27, 28

Cruzan v. Missouri,
497 U.S. 261 (1991) 15, 19

De Buono v. NYSA-ILA Med. & Clinical Servs. Fund,
520 U.S. 806 (1997) 14, 16

Garcia v. San Antonio Metro. Transit Auth.,
469 U.S. 528 (1985) 13

Gen. Dynamics Land Sys., Inc. v. Cline,
540 U.S. 581 (2004) 10

Gonzales v. Raich,
125 S. Ct. 2195 (2005) 9

Gregory v. Ashcroft,
501 U.S. 452 (1991) 12, 13

Linder v. United States,
268 U.S. 5 (1925) 15

New State Ice Co. v. Liebmann,
285 U.S. 262 (1932) 19

Oregon v. Ashcroft,
368 F.3d 1118, 1125 (9th Cir. 2004) 9

Oregon v. Ashcroft,
192 F. Supp. 2d 1077 (D. Or. 2002) 23, 24

Pegram v. Herdrich,
530 U.S. 211 (2000) 14, 16

Rush Prudential HMO, Inc. v. Moran,
536 U.S. 355 (2002) 13, 15

Solid Waste Agency v. United States Army Corps of Eng'rs, 531 U.S. 159 (2001) 13, 14

Swierkiewicz v. Sorema N.A.,
534 U.S. 506 (2002) 16

United States v. Lopez,
514 U.S. 549 (1995) 19, 23

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001) 26

Vacco v. Quill, 521 U.S. 873 (1997) 3, 23, 28, 29

Washington v. Glucksberg,
521 U.S. 702 (1997) ..... passim

Whalen v. Roe,
429 U.S. 589 (1977) 14

STATUTES, RULES, ACTS, AND REGULATIONS

21 C.F.R. § 1306.04 11

Act of June 4, 2001, ch. 358, part LL, 2001 Me. Legis. Serv. 358 (West) 22

Act of Oct. 5, 2001, ch. 518, 2001 Cal. Leg. Serv. 518 (West) 22

Anti-Drug Abuse Act of 1986, Pub. L. 99-570 10

Anti-Drug Abuse Amendments of 1988, Pub. L. 100-690 10

Assemb. B. 184, 95th Leg., 2001 Reg. Sess. (Wis. 2002) 21

Assemb. B. 417, 95th Leg., 2001 Reg. Sess. (Wis. 2002) 21

Assemb. B. 654 2005 Sess. (Cal. 2005) 21

Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513 10

Controlled Substances Act, 21 U.S.C. §§ 801-904 6

21 U.S.C. § 801(3) 9

21 U.S.C. § 801(6) 9

21 U.S.C. § 802(28) 16

21 U.S.C. § 802(29) 16

21 U.S.C. § 811 10

21 U.S.C. § 811(c) 10

21 U.S.C. § 812 10

21 U.S.C. § 812(b)(1)(A) 10

21 U.S.C. § 812(b)(1)(B) 10

21 U.S.C. § 812(b)(1)(C) 10

21 U.S.C. § 823(a)(2) 11

21 U.S.C. § 823(b)(2) 11

21 U.S.C. § 823(f) 17

21 U.S.C. § 823(g) 16

21 U.S.C. § 824(a)(4) 17

Controlled Substances Trafficking Prohibition Act, Pub. L. 105-277 10

Drug Addiction Treatment Act of 2000, Pub. L. 106-310 10

Education on Physician-Assisted Suicide, S. 390, 2001 Gen. Assem., Reg. Sess. (N.C. 2001) 22

Food, Drug, & Cosmetics Act, 21 U.S.C. § 301, *et seq.* 16

H. 168, 2006-06 Leg. Sess. (Vt. 2005) 21

H.R. 739 2004 Reg. Sess. (Ala. 2004) 21

H.R. 1209, 157th Gen. Court, 2001 Sess. (N.H. 2001) 21

H.R. 2487, 21st Leg., Reg. Sess. (Haw. 2002) 20

H.R. 4550, 182d Gen. Court, 2001-02 Sess. (Mass. 2001) 21

Juvenile Drug Trafficking Act of 1986, Pub. L. 99-570 10

Kan. Stat. Ann. § 60-4405 (2003) 21

Lethal Drug Abuse Prevention Act 12

Maine Death with Dignity Act, *available at* http://www.maine.gov/sos/cec/elec/2000g/refguide.htm (last visited July 6, 2005) 20

Narcotic Addict Treatment Act of 1974, Pub. L. 93-281 10

Ohio Rev. Code Ann. 3795.01 (West 2005) 21

Ohio Rev. Code Ann. 4731.22 (West 2005) 21

Oregon Death with Dignity Act, Or. Rev. Stat. §§ 127.800-127.897 ..... passim

Or. Rev. Stat. §§ 443.850-870 6

Pain Relief Promotion Act 12

S. 184, 2001-02 Leg., Reg. Sess. (Wis. 2001) 22

S. 389, 2001 Gen. Assem. (N.C. 2001) 21

S. 390, 2001 Gen. Assem. (N.C. 2001) 21

S. 636, 2002 Leg., Reg. Sess. (Fla. 2002) 22

S. 677, 224th Ann. Legis. Sess. (N.Y. 2002) 20

S. 1307, 23d Leg., Reg. Sess. (Haw. 2005) 21

S. 2745, 21st Leg., Reg. Sess. (Haw. 2002) 20

S. 2749, 21st Leg., Reg. Sess. (Haw. 2002) 21

S. 2763, Gen. Ass., Jan. Sess. (R.I. 2002) 21

Sup. Ct. R. 37.3(a) 1

Sup. Ct. R. 37.6 1

OTHER AUTHORITIES

ACP-ASIM, *ACP-ASIM Opposes Physician Assisted Suicide*, Nov. 1, 2000, *available at* http://www.acponline.org/college/pressroom/pas110100.htm (last visited July 6, 2005) 25

A. Doyle, *Silver Blaze*, *in* The Complete Sherlock Holmes 335 (1927) 17

Ann Alpers, *Criminal Act or Palliative Care?*, 26 J. L. Med. & Ethics 308 (1998) 26, 27

Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain*, 26 J. L. Med. & Ethics 332 ..... 26, 27

CMA House of Delegates Resolution 507a-95 2

CMA House of Delegates Resolution 516-97 2

C. Stratton Hill, Jr., *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287 (1996) 27

Center for Bioethics, Mar. 20, 2000, *Penn Bioethicists Lead National Panel on Assisted Suicide, at*

http://www.bioethics.upenn.edu/press/?pageId=13 (last visited July 6, 2005) 24

Ezekiel J. Emanuel et al., *Euthanasia and Physician-assisted Suicide*, 347 Lancet 1805 (1996) 23

H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566 ..... 15, 16

Howard Brody, *Physician-Assisted Suicide in the Courts*, 82 Minn. L. Rev. 939 (1998) 28

J. David Haddox & Gerald M. Aronoff, Commentary, *The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain*, 26 J. L. Med. & Ethics 350 (1998) 27

Jerald G. Bachman et al., *Attitudes of Michigan Physicians and the Public Toward Legalizing Physician-assisted Suicide and Voluntary Euthanasia*, 334 N. Engl. J. Med. 303 (1996) 23

Jerome Groopman, Harvard Medical School, *Separating Death from Agony*, N.Y. Times, Nov. 9, 2001 29

Joseph Cordaro, Note, *Who Defers to Whom?*, 70 Fordham L. Rev. 2477 (2002) 12

Katrina Hedberg et al., Letter to the Editor, *Legalized Physician-Assisted Suicide in Oregon, 2001*, 346 N. Engl. J. Med. 450 (2002) 22

Kenneth Jost, *The Right to Die*, 15 CQ Researcher 423 (2005) 23

Letter for the Honorable Henry Hyde from the Honorable Janet Reno, Attorney General of the United States (June 5, 1998) 18

Linda Ganzini et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care*, 285 J. Am. Med. Ass'n, 2363 (2001) 22

Margaret P. Miller, *Bootstrapping Down a Slippery Slope in the Second and Ninth Circuits*, 30 Creighton L. Rev. 833 (1997) 29

Marshall B. Kapp, *Treating Medical Charts Near the End of Life*, 28 U. Tol. L. Rev. 521 (1997) 26, 27

Melinda A. Lee et al., *Legalizing Assisted Suicide*, 334 N. Engl. J. Med. 310 (1996) 23

Michael J. Reynolds, Note, *Morphine or Malpractice*, 15 St. John's J. Legal Comment. 79 (2000) 27

Rima J. Oken, Note, *Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917 (2002) 27

Robert Steinbrook, Health Policy Reports, *Physician-Assisted Suicide in Oregon*, 346 N. Engl. J. Med. 460 (2002) 22

Sandra H. Johnson, *Disciplinary Actions and Pain Relief*, 24 J. Law, Med. & Ethics 319 (1996) 27

Simon N. Whitney et al., *Views of United States Physicians and Members of the American Medical Association House of Delegates on Physician-assisted Suicide*, 16 J. Gen. Internal Med. 290 (2001) ... 23

Timothy E. Quill et al., *The Rule of Double Effect*, 337 N. Engl. J. Med. 1768 (1997) 29

William McCall, *Assisted Suicide Cases Down in '04*, The Columbian, Mar. 11, 2005, at C2 ..... 22, 24

INTERESTS OF *AMICI CURIAE*[1]

The American Academy of Pain Management ("AAPM"), California Medical Association ("CMA"), American Geriatrics Society ("AGS"), San Francisco Medical Society ("SFMS"), Society of General Internal Medicine ("SGIM"), Washington State Medical Association ("WSMA"), Medical Society of the State of New York ("MSSNY"), American Medical Student Association ("AMSA"), American Medical Women's Association ("AMWA"), National Academy of Elder Law Attorneys, Inc. ("NAELA"), Southern California Cancer Pain Initiative ("SCCPI"), Washington State End of Life Consensus Coalition ("WSEOLCC"), Washington Intractable Chronic Pain Association ("WICPA"), National Foundation for the Treatment of Pain ("NFTP"), American Pain Foundation ("APF"), Oregon Hospice Association, Inc. ("OHA"), American Academy of HIV Medicine ("AAHIVM"), American Academy of Hospice and Palliative Medicine ("AAHPM"), and a coalition of distinguished individual pain, palliative, and elder care professionals respectfully submit this brief as *amici curiae* in support of Respondents.

AAPM is the largest multi-disciplinary pain society in the United States. AAPM is a nonprofit credentialing society for pain management practitioners; its goals are bringing together the many clinicians who work with individuals in pain and assisting in the provision of quality services to those individuals.

CMA is a nonprofit, incorporated professional association of more than 30,000 physicians practicing in

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[1] Pursuant to Sup. Ct. R. 37.3(a), the parties have consented to the filing of this brief and copies of the consent letters are submitted herewith. Pursuant to Sup. Ct. R. 37.6, counsel for *amici* states that this brief was not authored, in whole or in part, by any counsel for a party, and no person, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

California. CMA's membership includes California physicians engaged in the private practice of medicine, in all specialties. CMA's primary purposes are "to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession." CMA and its members share the objective of promoting high quality, cost-effective health care for Californians.[2]

AGS is a not-for-profit, organization of professionals who are specially trained in the management of care for frail, chronically ill, older patients. AGS is dedicated to improving the health, independence and quality of life of all older people. AGS promotes high quality, comprehensive and accessible care for America's older population, including those chronically ill and disabled.

SFMS is California's oldest medical association, having been first established just after the "gold rush" in the mid-1800s. A professional association for local physicians, SFMS is an advocate for physicians and their patients, providing education, advocacy, and referral information on a wide range of medical and public health topics. Well over 1,000 physicians of every medical specialty are members, and SFMS is represented on professional and government bodies throughout the city, state, and nation.

SGIM is a national association of over 3,000 physicians and other health professionals whose purpose is

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[2] As set forth in CMA's House of Delegates Resolutions 507a-95 and 516-97, CMA's current policy on physician assisted suicide is that, while physicians may diagnose a patient as having a terminal condition or illness and find a patient competent to make informed decisions, CMA continues to condemn voluntary active euthanasia by physicians as unethical and unacceptable. While opposition to the legalization of physician-assisted suicide remains the position of CMA, CMA remains receptive to multiple views and perspectives expressed by various participants in the public discourse on this issue and actively seeks input from all stakeholders in this important societal dialogue.

improving patient care, education and research in general internal medicine.

WSMA is a private, non-profit membership organization that represents over 9,000 physicians, residents, medical students, and physician-assistants throughout Washington. WSMA represents the professional interests of all member physicians, and promotes effective physician leadership in the evolving health care delivery system.

MSSNY, organized in 1807 and incorporated and operated under New York's Not-for-Profit Corporation Law, has approximately 27,000 physician, medical resident and medical student members, representing all medical specialties. The purposes of MSSNY include "[t]o enhance the delivery of medical care of high quality to all people in the most economical manner, and to act to promote and maintain high standards in medical education and in the practice of medicine in an effort to ensure that quality medical care is available to the public."[3]

AMSA is the nation's largest independent organization of physicians-in-training. Founded in 1950, AMSA is a non-profit organization that represents over two-thirds of all medical students and a total of 60,000 physicians-in-training. AMSA has chapters in every allopathic and osteopathic medical school in the country, and indeed represents the future of medicine in the United States.

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[3] MSSNY joins this brief despite its well-documented opposition to physician-assisted suicide—MSSNY joined *amicus* briefs in support of petitioners' eventually successful efforts to uphold state statutory bans on physician-assisted suicide in both *Vacco v. Quill*, 521 U.S. 793 (1997), and *Washington v. Glucksburg*, 521 U.S. 702 (1997). MSSNY shares the concern of the other *amici* here about (1) the Attorney General's unauthorized encroachment on the states' traditional regulation of medical practice and (2) the potential chilling effect of the Attorney General's Directive on physicians' willingness to administer proper palliative care.

AMSA's goal is to improve medical training and the nation's health.

AMWA is a non-profit association founded in 1915 to advance women in medicine and improve women's health. AMWA is the oldest and largest multispecialty organization of women physicians and health care professionals. AMWA empowers women to lead in improving health for all within a model that reflects the unique perspective of women.

NAELA is a non-profit association that assists lawyers, bar organizations, and others who work with older clients and their families. Established in 1987, NAELA provides information, education, networking and assistance to those who deal with the many specialized issues involved with providing legal services to the elderly and disabled. Its mission is to establish its members as the premier providers of legal advocacy, guidance, and services to enhance the lives of people as they age. Its members counsel older adults and families facing decisions on how to cope with serious chronic illness and ultimately decisions about end-of-life.

SCCPI, founded in 1993, is a nonprofit volunteer interdisciplinary organization made up of physicians, nurses, pharmacists, social workers and many other professionals dedicated to the relief of cancer pain. SCCPI works closely with other professional and regulatory agencies to remove barriers to optimum pain relief. SCCPI currently has approximately 2,200 individual members.

WSEOLCC's mission is to work collaboratively with organizations and individuals across Washington to develop and support innovative approaches for achieving excellence in care of the dying and to foster dialogue about death and dying within our communities. Since 1997, WSEOLCC, working together with the WSMA, has provided an ongoing venue for members from all communities in Washington to explore end of life issues together.

WICPA is a nonprofit educational and advocacy organization founded in 1991 that represents over 700 patients and physicians in the Pacific Northwest. WICPA assists intractable chronic pain sufferers to regain their self-respect, maintain their dignity, and receive treatment as necessary to allow each to function as normally as possible. Its purpose is to lessen the suffering of people with chronic pain by educating pain sufferers, physicians, and the public about intractable chronic pain and its management.

NFTP is a not-for-profit national organization that provides support for patients suffering from intractable pain, their families, friends, and their physicians through advocacy and education. NFTP's website, www.paincare.org, receives as many as 10,000 individual visits per day. NFTP also assists persons who cannot find physicians to treat their pain, supports those whose physicians refuse to treat them out of fear of sanctions and prosecution, and provides opportunities for people suffering from intractable pain to share their experiences with one another. These activities provide NFTP with a multidimensional understanding of how recent efforts by law enforcement to substitute its own judgment about the legitimate purposes medical decisions for those laid out professional guidelines, medical ethics and evidence-based clinical experience.

APF is the nation's largest nonprofit organization devoted exclusively to serving the needs of people with chronic and acute pain. Its mission is to improve the quality of life for all Americans with pain by raising public awareness, providing practical information, promoting research, and advocating removal of barriers to effective pain management. Its website, www.painfoundation.org, is a respected resource for patients and professionals alike. Through its outreach and patient support activities, APF is well-informed on the conditions under which those with chronic pain in must seek care.

OHA is a statewide, public benefit, nonprofit voluntary membership organization dedicated to ensuring and promoting high quality hospice and palliative care. OHA's first responsibility is to the public. In addition to public information, referral and advocacy, OHA provides education and technical assistance to more than 50 operating and developing hospice provider programs who are or will be serving dying Oregonians and their families and loved ones. OHA was authorized by Oregon to keep Oregon's Hospice Registry and is recognized as an accrediting body for hospices in legislation passed in 1987. In 1992, OHA was assigned authority by the legislature to ensure compliance with Or. Rev. Stat. §§ 443.850-870, Oregon's regulatory scheme for hospice programs.

AAHIVM is an independent organization of HIV specialists and others dedicated to promoting excellence for all patients in HIV/AIDS care. As the largest independent organization of HIV frontline providers, AAHIVM's 2,000 members provide direct care to more than 340,000 HIV patients—more than two thirds of the patients in active treatment for HIV disease.

AAHPM is an organization of physicians and other medical professionals dedicated to excellence in and the advancement of palliative medicine through prevention and relief of patient and family suffering by providing education and clinical practice standards, fostering research, facilitating personal and professional development, and by public policy advocacy.

The individual *amici* are licensed medical professionals and educators with substantial expertise in confronting pain management and end-of-life issues faced by terminally ill patients.[4]

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[4] *See* Addendum A for a fuller description of each of the individual *amici*.

SUMMARY OF THE ARGUMENT

We respectfully urge the Court to affirm the decision of the Court of Appeals permanently enjoining enforcement of the Directive issued by the Attorney General ("AG") interpreting the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-904, to preclude physicians from taking actions consistent with the Oregon Death With Dignity Act ("ODWDA"), Or. Rev. Stat. §§127.800-127.897.

The Directive, an agency statement issued with no public comment, directs the Drug Enforcement Administration ("DEA") to investigate and prosecute physicians who prescribe medications to terminally ill patients that hastens their deaths consistent with the detailed requirements of democratically-enacted state legislation. The AG's unprecedented and unilateral determination upsets a longstanding tradition of deference to state regulation of medical practice while interfering with both the ODWDA and physicians' ability to care for terminally ill patients nationwide. The Directive will also cut off a robust political debate explicitly sanctioned by this Court. Finally, the Government's amorphous justification for the Directive will, by its very breadth and vagueness, cast a pall over physicians' decisionmaking. Confronted with the formidable possibility of medically untrained enforcement officers shadowing their decisionmaking, physicians will retreat from their obligations to their terminally ill patients.

ARGUMENT

With the ODWDA, Oregon voters enacted a law that allows, in some circumstances and under careful criteria, a physician to prescribe medication that has the effect of hastening the death of terminally ill patients. The AG does not agree and has sought to overturn this statute by creating, in the Directive, a result-oriented and indefensible interpretation of a decades-old federal statute, the CSA, with the result being that the AG now claims the authority to

determine the confines of legitimate medical practice. Until the Directive, it had never been seriously contemplated that the CSA permits the federal government to unilaterally replace the states as regulators of the medical profession. Yet, the AG has relegated to himself the exclusive right both to define what a legitimate medical practice is and to prosecute purported violators. He simply cannot do this.

First, the text of the CSA does not in any way delegate such extraordinary power to the AG. The CSA delegates to the AG the authority to combat drug abuse and the illicit traffic of controlled substances—not the authority to regulate the practice of medicine generally. Indeed, far from being at odds with the ODWDA, the CSA contemplates that, under proper medical supervision and under *state* regulation, doctors *can* prescribe controlled substances to alleviate pain. Second, the Directive alters the federal-state balance without a grant of authority by Congress, thus destroying this Court's promise of a state-level resolution to this important public policy issue. The serious constitutional problems raised by the AG's argument give added force to an interpretation of the CSA that allows states to continue their historical role as regulators of the medical profession. Third, the Directive would unavoidably have a profoundly chilling effect on physicians' medical judgment. Faced with prosecution, physicians will err on the side of caution and undertreat chronic and irreversible pain sufferers.

Moreover, the Directive will stall the development of medical knowledge in the end-of-life and palliative care fields. While the merits of physician-assisted suicide can, and should, be debated, the states should be permitted to determine policy for their own medical communities.

I. THE TEXT OF THE CSA DOES NOT CONFLICT WITH THE ODWDA

The AG's primary argument is that the federal scheme established by the CSA for the regulation of the

distribution of controlled substances includes the power to define the "legitimate medical purpose[s]" for which controlled substances can be prescribed. *See* Br. for Pet'rs at 14-18. To the contrary, the text of the CSA, settled canons of statutory construction, and over 100 years of deference to state regulation of medical practices have placed the regulation of legitimate medical practice with the states. The text of the CSA "provide[s] no indication—much less an 'unmistakably clear' indication—that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide." *Oregon v. Ashcroft*, 368 F.3d 1118, 1125 (9th Cir. 2004). Rather, the CSA delegates to the AG only the authority to regulate controlled substances as necessary to combat drug abuse and drug trafficking.

As this Court recently noted, the CSA was "the first campaign" of a "national 'war on drugs.'" *Gonzalez v. Raich*, 125 S. Ct. 2195, 2201 (2005). "Congress set out to enact legislation that would . . . provide meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthen law enforcement tools against the traffic in illicit drugs." *Id.* It thus cannot be doubted that "[t]he main objectives of the CSA were to conquer drug abuse and to control legitimate and illegitimate traffic in controlled substances," *id.* at 2203, and not the wholesale regulation of medical practice.

Indeed, the text of CSA itself clearly evidences its purpose to be the prevention of drug abuse and trafficking, rather than general regulation of medical practice. The Congressional findings within the CSA that recite that "[a] major portion of the *traffic* in controlled substances flows through interstate and foreign commerce," and that "[f]ederal control of the intrastate incidents of *traffic* in controlled substances is essential to the effective control of the interstate incidents of such *traffic*." 21 U.S.C. §§ 801(3) & (6) (emphases added). This purpose is even exhibited by the titles of the acts and amendments passed by Congress. For

example, the 1970 act of which the CSA was one part, Pub. L. 91-513, was named the Comprehensive Drug Abuse Prevention and Control Act of 1970. Similarly, the 1974 amendments were enacted through the Narcotic Addict Treatment Act of 1974, Pub. L. 93-281; the 1986 amendments included the Juvenile Drug Trafficking Act of 1986, Pub. L. 99-570, and the Anti-Drug Abuse Act of 1986, Pub. L. 99-570.[5]

To combat the illicit drug trade, the CSA authorizes the AG to place a drug on one of five schedules of controlled substances and to regulate their distribution. *See* 21 U.S.C. § 811. In deciding whether or not to schedule a drug at all, the AG must evaluate eight Congressionally-defined factors. *See* 21 U.S.C. § 811(c). *Each* of these factors speaks to the potential for a drug to be abused and/or to lead to dependence. *Id.* *None* of these factors depends on the potential medical uses, legitimate or otherwise, of a drug. *Id.*

After a determination to schedule a drug under § 811, Congress, in § 812, required three findings to determine the proper schedule. The first finding relates to the "potential for abuse." *See, e.g.*, § 812(b)(1)(A). The third finding similarly relates to the potential for "psychological or physical dependence." *See, e.g.*, § 812(b)(1)(C). The second finding, whether or not the drug has a "currently accepted medical use," *see, e.g.*, § 812 (b)(1)(B), must be read in light of the context of these other two required findings. *See Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 596 (2004) (noting "the cardinal rule that a statutory phrase must be read in context since a phrase gathers meaning from the words around it" (internal quotations and alterations omitted)). In an act directed at limiting drug trafficking and abuse, and sandwiched between two provisions directing the AG to

[5] *See also, e.g.*, Drug Addiction Treatment Act of 2000, Pub. L. 106-310; Controlled Substances Trafficking Prohibition Act , Pub. L. 105-277; Anti-Drug Abuse Amendments of 1988, Pub. L. 100-690.

determine the potential for abuse and addictive properties of a drug, the AG's authority to determine whether a drug has an "accepted medical use," logically must be interpreted to authorize a determination of whether there is any accepted medical use other than the facilitation of drug abuse. Congress, when instructing the AG to determine whether a controlled substance has an "accepted medical use" thus did not intend to give the AG the ability to determine the propriety of the various medical uses of medications.

Nor does 21 C.F.R. § 1306.04, which directs the AG to prohibit a practitioner from prescribing controlled substances except for a "legitimate medical purpose," give the AG the authority for the wholesale regulation of the practice of medicine. This phrase, read in the context of the CSA, differentiates between prescriptions made with the legitimate medical interests of patients in mind and those made to further drug abuse, addiction, and trafficking.

Every case the AG cites for the proposition that courts have "recognized and enforced the CSA's prohibition on the prescription of controlled substances for other than legitimate medical purposes" involves cases where physicians prescribed medications in a manner that could aide drug abusers. *See* Br. of Pet'rs at 16-17. Conversely, where a prescription is written for a *bona fide* medical purpose, the AG cannot unilaterally determine that medical purpose to be illegitimate. Instead, the AG must defer to the states and state standards of medical care—areas firmly within the states' traditional regulation of the practice of medicine. *See infra* Part II. Indeed, Congress included in the CSA specific references to state regulation. For example, § 823(a)(2) & (b)(2) instruct the AG to consider "compliance with applicable State and local law" when registering manufacturers and distributors. Similarly, § 824(a)(3) instructs the AG to consider whether a physician is "authorized by State law to engage in the manufacturing,

distribution, or dispensing of controlled substances" when making a physician registration determination.

Even if the CSA were ambiguous—and it is not—"to give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which [this Court] relied to protect states' interests." *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991) (internal quotation omitted) (alteration in original).[6] "Traditional tools of statutory construction" preclude the AG's interpretation because the CSA shows no intent to take away the states' power to regulate medicine. *See Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984) ("If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect."). Specifically, when viewed in light of the traditional reservation of the regulation of medicine to the states, the presumption against alterations in the federal-state balance and the canon of constitutional avoidance compel the conclusion that the AG has no authority to define "legitimate medical practice."

II. WELL-ENTRENCHED PRINCIPLES OF FEDERALISM PRECLUDE INTERPRETING THE CSA TO PERMIT THE AG'S INTRUSION INTO AN AREA TRADITIONALLY RESERVED TO THE STATES

Any potential interpretation of a federal statute that intrudes into an area traditionally reserved to the states must be scrutinized in the context of our uniquely compound system of government. Through the division of political

[6] Recently, Congress has twice rejected federal proscription of physician-assisted suicide by failing to enact bills substantially similar to the Directive. *See* Joseph Cordaro, Note, *Who Defers to Whom?*, 70 Fordham L. Rev. 2477, 2485-86 (2002) (recounting the defeats of the Lethal Drug Abuse Prevention Act and the Pain Relief Promotion Act).

power between the states and the federal government, federalism helps secure several important values: "It assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry." *Gregory v. Ashcroft*, 501 U.S. at 458 (citations omitted). "The essence of our federal system," according to Justice Blackmun, "is that . . . the States must be equally free to engage in any activity that their citizens choose for the common weal, no matter how unorthodox or unnecessary anyone else . . . deems state involvement to be." *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 546 (1985).

To ensure respect for this federalist structure, even where Congress' power to legislate is undisputed, this Court has insisted that before a law invades the states' traditional province, Congress must clearly express its intent to do so. *See Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365-66 (2002); *Solid Waste Agency v. United States Army Corps of Eng'rs*, 531 U.S. 159, 172-73 (2001); *Gregory v. Ashcroft*, 501 U.S. at 460 (infringing on "state governmental functions" is "a power that we must assume Congress does not exercise lightly").

In a recent case strikingly similar to this one, where a federal agency sought to extend the reach of a statute into an area traditionally reserved to the states, this Court reaffirmed these principles. In *Solid Waste Agency*, the Army Corps of Engineers ("Corps") sought to expand federal power to regulate "navigable waters" under the Clean Water Act ("CWA") to include intrastate waters used as habitat by migratory birds. The Court refused to allow this interpretation of "navigable waters", reasoning in part that such an interpretation was disfavored in that it would encroach into an area traditionally reserved to the states:

> Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. This requirement stems from . . . our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority. This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power. Thus, where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.

Solid Waste Agency, 531 U.S. at 172-73 (citations and internal quotation omitted). Here, not only is there no clear Congressional intent to give the AG the power he claims, but it is also settled law that the regulation of medical practice is a traditional state power.

A. THE REGULATION OF MEDICINE IS A TRADITIONAL STATE FUNCTION

This Court has long recognized that the regulation of legitimate medical practice is within the states' province. *See Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) ("[H]ealth care" is a "subject of traditional state regulation"); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) ("[T]he historic police powers of the State include the regulation of matters of health and safety."); *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977) ("It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the

health professions."). As early as 1925, this Court overturned a federal conviction that purported to discern the intent of a physician in prescribing medicine. In that case, *Linder v. United States*, 268 U.S. 5 (1925), the Government prosecuted a doctor for dispensing illegal drugs to an addict under the Harrison Act, the CSA's predecessor statute; this Court reversed the doctor's conviction. In doing so, this Court noted that "direct control of medical practice in the states is beyond the power of the Federal Government." *Id.* at 18. The CSA has not changed this balance. Thus, in 2002, this Court called "the field of health care" "a subject of traditional state regulation," in discussing "quintessentially state-law standards of reasonable medical care." *Rush Prudential*, 536 U.S. at 387 (quotations omitted).

This Court has likewise affirmed the states to be the primary regulators of medicine in the context of the treatment of the incapacitated and terminally ill. In *Cruzan v. Missouri*, 497 U.S. 261 (1991), this Court addressed a constitutional challenge to a state's refusal of a family's request to take a patient off life-support. The State argued that the regulation of medicine was an area reserved to the states. This Court agreed, affirming states' rights to define legitimate medical practice. More recently, in *Washington v. Glucksberg*, 521 U.S. 702 (1997), this Court declared that, within constitutional limits, the states are the appropriate forum for decisions about assisted suicide. *See id.* at 728-36. Together, these decisions evidence a strong preference for continuing the tradition of state regulation of medicine.

Only when Congress declares a clear intent to intrude into the states' regulation of medicine will this preference be disturbed. The AG can point to no such intent. The CSA was enacted to confront the illegal drug trade, not to nationalize the regulation of medicine. *See supra* Part I. The House Report states that the CSA was "designed to deal . . . with the growing menace of drug abuse." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

That "menace" consisted of the deleterious effects of drugs like cocaine and consequential crime. *Id.* at 4572-75. The CSA therefore created a "closed system" to "reduce the widespread diversion of these drugs out of legitimate channels into the illicit market." *Id.* at 4572. In other words, the CSA prevents drug *abuse* by regulating drug distribution; it does not regulate drug *use* within legitimate channels. Congress thus drew a careful line between regulating the drug trade and regulating the medical profession. To interpret the CSA to permit the regulation of pain care would erase this line and turn the statute on its head.[7]

As the AG points out, the CSA does provide for broader regulation in one medical area—"maintenance" and "detoxification" treatment of addicts. *See* Br. for Pet'rs 33-34 (§§ 802(28) & (29)). However, the treatment of drug abusers is directly related to the CSA's express purpose and Congress gave explicit authority for the regulation of these programs in the text.[8] Even in these provisions, Congress empowered the Secretary of Health and Human Services ("HHS") to regulate—not the AG. *See* 21 U.S.C. § 823(g).

There is thus *nothing* in the statute or its legislative history to suggest that Congress wanted the AG to second-guess the states' delineation of legitimate medical practice.[9]

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[7] Congress drew, and this Court has given effect, to a similar delineation between federal regulation of employee health benefit plans under ERISA and state control over the healthcare professions. *See Pegram*, 530 U.S. at 236; *De Buono*, 520 U.S. at 814.

[8] *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002) ("exclussio unius est exclusio alterius").

[9] Even the FDCA, 21 U.S.C. § 301, *et seq.*, while authorizing the FDA to approve drugs for a specific medical purpose, does not empower the FDA to prevent physicians from prescribing those medications for unapproved, or "off-label," medical uses. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) ("'[O]ff-label' usage . . . is an accepted and necessary corollary of the FDA's mission to

If Congress had intended such sweeping changes in the balance of state and federal power, it would certainly make such intent clear.[10] The authority to prosecute doctors for violating a professional standard is hardly the same thing as defining what the standard is. It is analogous to a highway patrolman conferring to him or herself the power not only to enforce the speed limit but also to decide what the speed limit should be. One therefore cannot convert the DEA's power to *apply* a rule into the power to *create* a rule.

The AG also relies on the 1984 amendments that enlarged the grounds for revocation of a physician's registration. *See* Br. for Pet'rs at 34-35. Section 824(a)(4), as amended, permits the AG to terminate a registration if that registration is "inconsistent with the public interest." Section 823 provides five factors that the AG must consider. Two of the factors involve the registrant's compliance with state or federal law. A third is a catch-all provision. The other factor relevant here instructs the AG to look to the acts of the physician's *state* licensing authority.[11] Of course, state licensing authorities define their own standards of legitimate medical practice. None of these factors suggest that Congress sought to regulate medicine or to permit the AG to define legitimate medical practice nationally. Indeed, in 1998—more than a decade after the amendments—the Justice Department issued an opinion stating that "[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a State's determination as to what constitutes

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regulate in this area without directly interfering with the practice of medicine.").

[10] *See Chisom v. Roemer*, 501 U.S. 380, 396 n.23 (1991) ("Congress' silence in this regard can be likened to the dog that did not bark. *See* A. Doyle, *Silver Blaze*, *in* The Complete Sherlock Holmes 335 (1927).")

[11] 21 U.S.C. §§ 823(f).

legitimate medical practice in the absence of a federal law prohibiting that practice."[12]

In its about-face that came with the change of administration, the AG now claims that the 1984 amendments' "public interest" criterion permits it to define legitimate medical practice. But the AG could always revoke registrations once certain prerequisites were met. Expanding the statute's reach over physicians' registrations cannot plausibly be equated with granting the Federal government additional powers to define what is legitimate medical treatment. In fact, as the one case interpreting the public interest criterion has held, the amendments did not expand the areas in which the AG could regulate.

In that case, *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997), plaintiffs sought a preliminary injunction precluding the AG from taking action against physicians for discussing medical uses of marijuana. The AG argued that the CSA gave the DEA "broad authority" to "revoke a physician's license for any act that violates the public interest." *Id.* at 699. The court squarely rejected this contention, finding that the "public interest" criterion did not permit the AG to create standards for appropriate medical treatment. To the contrary, the court concluded, "only convictions or uncharged criminal activity in violation of federal, state, or local law would suffice to establish a violation of the public interest." *Id.* at 700.

As *Conant* demonstrates, there is no basis for inferring that the "public interest" criterion allows the AG to determine the legitimacy of a medical practice: By finding that the public interest criterion is limited to violations of existing law, the *Conant* court correctly determined that the amendments left the historic federal-state balance intact.

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[12] Letter for the Hon. Henry Hyde from the Hon. Janet Reno, Attorney General of the United States (June 5, 1998).

B. THE DIRECTIVE IMPEDES THE EXERCISE OF THIS TRADITIONAL STATE FUNCTION AND THWARTS THE ABILITY OF THE STATES TO ACT AS LABORATORIES OF DEMOCRACY

The Directive not only conflicts with the legislation it seeks to execute, but also impedes the states' ability to act as laboratories for the development of public policy. Justice Brandeis expressed this system's genius: "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Echoing this view, Justice Kennedy observed that "the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring).

This Court has encouraged state experimentation in the area of care for the terminally ill or incapacitated. In *Cruzan*, Justice O'Connor emphasized that such deference is the *best* way for society to balance the various interests in end-of-life decisionmaking: "Today we decide only that one State's practice does not violate the Constitution; the more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the 'laboratory' of the States." 497 U.S. at 292 (O'Connor, J., concurring) (citation omitted).

More recently, in cases addressing the constitutionality of assisted suicide, this Court noted that "Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue,

as it should in a democratic society." *Glucksburg*, 521 U.S. at 735. The majority noted with approval the deliberation of many states on the subject: "States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Id.* at 716-19. Justice O'Connor likewise elaborated: "As the Court recognizes, states are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. *In such circumstances, the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the laboratory of the States.*" *Id.* at 737 (O'Connor, J., concurring) (citations and internal quotation omitted) (emphasis added); *see also id.* at 786-89 (Souter, J., concurring).

In line with this Court's suggestions, Oregonians have repeatedly examined the issues surrounding assisted death. The state's citizens enacted the ODWDA in 1994 by majority vote. During a court challenge to the ODWDA, the legislature put the issue back before the voters. Oregonians reaffirmed their decision by a 60% to 40% vote. *The question is not whether one agrees with the substance of Oregon's decision*; the question is whether Oregon has acted in the fashion this Court mandated. It unquestionably did.

Significantly, the Directive endangers not only Oregon's legislative process, but also the many varied efforts undertaken by state legislatures around the country. A number of states—New York,[13] Maine,[14] Hawaii,[15] and Rhode Island[16]—are currently considering or recently considered statutes similar to the ODWDA. Just this year, the California Legislature referred a bill, modeled on the ODWDA, to the House Committee on Appropriations where it passed 11 to 6 after amendment,[17] while the Vermont Legislature heard testimony on a bill that would mirror the ODWDA.[18]

Conversely, many states, including North Carolina,[19] Massachusetts,[20] and Alabama,[21] have enacted or are considering bills that would criminalize physician-assisted suicide. Some states, like Ohio, have made it subject to medical board disciplinary action,[22] while others, like Kansas, have created a civil cause of action against physicians who assist a suicide.[23] New Hampshire[24] and Wisconsin[25] both considered laws allowing physicians to

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[13] *See* S. 677, 224th Ann. Legis. Sess. (N.Y. 2002).

[14] *See* Maine Death with Dignity Act, *available at* http://www.maine.gov/sos/cec/elec/2000g/refguide.htm (last visited July 6, 2005) (the referendum failed 49% to 51%).

[15] *See* S. 2745, 22nd Leg., Reg. Sess. (Haw. 2002); H.R. 2487, 21st Leg., Reg. Sess. (Haw. 2002). H.R. 2487 passed the House, but did not pass in the Senate. S. 2745 failed to pass the Senate by a margin of 11 to 14. In January 2005, the Senate introduced another bill modeled on the ODWDA to the Committee on Health. *See* S. 1307, 23d Leg., Reg. Sess. (Haw. 2005). Hawaii also considered a ballot initiative to amend its constitution. *See* S. 2749, 21st Leg., Reg. Sess. (Haw. 2002).

[16] *See* S. 2763, Gen. Ass., Jan. Sess. (R.I. 2002).

[17] *See* Assemb. B. 654 2005 Sess. (Cal. 2005). The bill also passed the Committee on Judiciary with amendment 5 to 4.

[18] *See* H. 168, 2005-06 Leg. Sess. (Vt. 2005).

[19] *See, e.g.*, S. 389 & 390, 2001 Gen. Assem. (N.C. 2001).

[20] *See* H.R. 4550, 182d Gen. Court, 2001-02 Sess. (Mass. 2001). The House Committee determined H.R. 4550 eligible for Executive Session.

[21] *See* H.R. 739 2004 Reg. Sess. (Ala. 2004).

[22] *See* Ohio Rev. Code Ann. 4731.22 and 3795.01 (West 2005).

[23] *See, e.g.*, Kan. Stat. Ann. § 60-4405 (2003).

[24] *See* H.R. 1209, 157th Gen. Court, 2001 Sess. (N.H. 2001). The bill did not pass the house.

[25] Assemb. B. 417, 95th Leg., 2001 Reg. Sess. (Wis. 2002); Assemb. B. 184, 95th Leg., 2001 Reg. Sess. (Wis. 2002). Both bills failed to pass pursuant to a Senate Joint Resolution. Notably, Wisconsin considered similar legislation in tandem with a bills legalizing such treatment (which

refuse physician-assisted suicide on moral grounds without adverse employment repercussions. Finally, states are increasing education on end-of-life care issues.[26]

Here, Oregon's role becomes especially important; it is the only jurisdiction that can provide any statistical evidence.[27] Regardless of one's position, the ODWDA has provided and continues to provide useful empirical evidence.[28] This would be lost, though, if executive fiat replaces legislative (and popular) deliberation. In *Glucksberg*, Justice Souter noted that the states "have superior opportunities to obtain the facts necessary for a judgment about the [instant] controversy." *Glucksberg*, 521 U.S. at 788 (Souter, J., concurring). The paucity of data prompted the Justices to suggest that the states perform their traditional roles as experimenters. Justice Souter noted: "The day may come when we can say with some assurance which side is right, but for now it is the substantiality of the factual disagreement, and the alternatives for resolving it, that matter." *Id.* at 786. Here, the states must be permitted to play "their role as laboratories for experimentation . . . where the best solution is far from clear." *Lopez*, 514 U.S. at 581 (Kennedy, J., concurring); *see also Vacco v. Quill*, 521 U.S. 793, 806-808 (1997) (recounting the development New York's laws concerning assisted-suicide and refusal of treatment).

These debates embody Justice Brandeis' observation about federalism's utility; each state is developing a largely unique response to a public policy issue of great importance. There is no consensus yet, either among state legislatures or within the medical field. As the District Court noted, "[w]ithout doubt there is a tremendous disagreement among highly respected medical practitioners as to whether assisted suicide or hastened death is a legitimate medical practice."[29]

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also failed to pass pursuant to a Senate Joint Resolution). *See* S. 184, 2001-02 Leg., Reg. Sess. (Wis. 2001).

[26] *See, e.g.*, Act of June 4, 2001, ch. 358, part LL, 2001 Me. Legis. Serv. 358 (West); Act of Oct. 5, 2001, ch. 518, 2001 Cal. Leg. Serv. 518 (West); Education on Physician-Assisted Suicide, S. 390, 2001 Gen. Assem., Reg. Sess. (N.C. 2001); S. 636, 2002 Leg., Reg. Sess. (Fla. 2002).

[27] For example, Oregon's experience has *not* borne out predictions by detractors that the ODWDA would have a negative effect on pain management. *See, e.g.*, Linda Ganzini et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care*, 285 J. Am. Med. Ass'n 2363, 2365 (2001). Nor after nearly seven years has the ODWDA lead to the abuse predicted by some. *See* William McCall, *Assisted Suicide Cases Down in '04*, The Columbian, Mar. 11, 2005, at C2 ("There is no evidence of abuse or coercion or misuse of the [ODWDA] policy."); *see also* Katrina Hedberg et al., Letter to the Editor, *Legalized Physician-Assisted Suicide in Oregon, 2001*, 346 N. Engl. J. Med., Vol. 450, 450-52 (2002); Robert Steinbrook, Health Policy Reports, *Physician-Assisted Suicide in Oregon*, 346 N. Engl. J. Med. 460, 462 (2002) ("Despite predictions of wide use, only a small number of patients in Oregon have received prescriptions for lethal doses of medication . . . ."); *id.* ("According to the Oregon Health Division, there is no evidence that the law has been abused.").

[28] *See, e.g.*, Ganzini, *supra*, at 2369 ("Studies from Oregon offer a rare opportunity to examine changes in end-of-life care in the context of legalized assisted suicide.").

[29] Surveys show that the medical community is neither universally for nor universally against the practice. In a recent nationwide survey of physicians, "45% believed that physician-assisted suicide should definitely or probably be legal, 34% believed that it should definitely or probably be illegal, and 22% were uncertain." Simon N. Whitney et al., *Views of United States Physicians and Members of the American Medical Association House of Delegates on Physician-assisted Suicide*, 16 J. Gen. Internal Med. 290, 292-93 (2001). Other surveys have reported conflicting results. *See, e.g.*, Jerald G. Bachman et al., *Attitudes of Michigan Physicians and the Public Toward Legalizing Physician-assisted Suicide and Voluntary Euthanasia*, 334 N. Engl. J. Med., Vol. 303 (1996); Ezekiel Emanuel et al., *Euthanasia and Physician-assisted Suicide*, 347 Lancet 1805 (1996); Melinda A. Lee *et al.*, *Legalizing Assisted Suicide*, 334 N. Engl. J. Med. 310 (1996). Recent survey data indicates that the public supports pain alleviation treatment that hastens death. *See, e.g.*, Kenneth Jost, *The Right to Die*, 15 CQ Researcher 423, 428-29 (2005) (reporting a May 2003 Gallup survey finding that 72% of

Oregon v. Ashcroft, 192 F. Supp. 2d 1077, 1092 (D. Ore. 2002). Yet, this state-level discussion is precisely what this Court recognized as the appropriate forum for exploring such issues. The Directive threatens to foreclose further democratic deliberation through executive edict.

C. THE DIRECTIVE DIMINISHES DISCOURSE ON THE ETHICAL AND PRACTICAL IMPLICATIONS OF PHYSICIAN-ASSISTED SUICIDE

A clear benefit of the state-level debate is that medical professionals—those with the most experience, knowledge, and understanding of these difficult issues—have been able to speak their minds, deliberate upon the difficult issues at stake, propose public policy, and work with states on legislation. For example, the Center for Bioethics at the University of Pennsylvania Health System convened a national panel of experts on assisted-suicide. "The panel's goal was not to argue pros and cons, but to find common ground in examining how to guide practices and determine safeguards that would keep assisted suicide voluntary, regulated, and an option of last resort."[30] As Project Director Lois Snyder explained, the impetus behind the project was that "[t]he public, physicians, and policymakers clearly want—and need—thoughtful direction."[31] Recently the Center's Director, Arthur Caplan, commented on the ODWDA, stating that the "data confirms, for the seventh year, that the policy in Oregon is working. There is no evidence of abuse or coercion or misuse of the policy." William McCall, *supra*, at C2.

Americans agree that doctors should be allowed to end a terminal patient's life "by some painless means if the patient requests it.").

[30] Center for Bioethics, *Penn Bioethicists Lead National Panel on Assisted Suicide*, Mar. 20, 2000, *available at* http://www.bioethics.upenn.edu/press/?pageId=13 (last visited July 6, 2005).

[31] *Id.*

Another notable contribution is the Consensus Panel on End-of-Life Care begun in 1997 by the American College of Physicians—American Society of Internal Medicine.[32] The Panel's goal has been "to develop papers on the care of the dying under the College's Center for Ethics and Professionalism. The papers are used as training guides in conferences, hospital seminars, medical training programs and professional meetings."[33]

Implementation of the Directive will cause doctors to refuse to speak for fear of unwanted scrutiny from law enforcement, thereby freezing the democratic process essential to arriving at legitimate public policy.

III. THE DIRECTIVE WILL INTERFERE WITH PAIN MANAGEMENT DECISIONS

As demonstrated above, the Directive adversely impacts policy development in this difficult area. Equally important is its effect on the practice of medicine. The intrusion of an ill-equipped DEA into the oversight of physicians' decision-making creates fear among physicians who treat terminally ill patients. Moreover, the potential scope of the Directive, if upheld, makes it difficult for physicians to determine what conduct runs afoul of the law. Several features of the Directive are especially alarming.

First, by claiming the power to define "legitimate medical purpose," the AG seeks to vastly expand his jurisdiction over medicine. Indeed, the very notion that the AG is now empowered to determine the legitimacy of a particular medical practice is itself sufficient to cause

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[32] *See* ACP-ASIM, *ACP-ASIM Opposes Physician Assisted Suicide*, Nov. 1, 2000, *available at* http://www.acponline.org/college/pressroom/pas110100.htm (last visited July 6, 2005).

[33] *Id.*

alarm.[34] Until now, the DEA has not asserted that it alone can determine that otherwise appropriate state-sanctioned treatment is criminal.[35] The Directive gives doctors a short menu of unpalatable choices: undermedicate to avoid second-guessing by the DEA (harming patients); medicate pursuant to full disclosure (risking prosecution); or medicate and lie (again risking prosecution). Nothing in the CSA demands this choice; only the Directive forces physicians to choose between their patients and their freedom.

The threat of prosecution is not a trivial concern; investigations alone can result in the loss of reputation and privileges similar to the loss of a license.[36] Some physicians already practice "defensive medicine" in this area because of anxieties about legal repercussions.[37] Even a few prosecutions would lead physicians to "act on the perception that they are going to get into trouble. And as a result the

[34] Bringing the DEA into this context is a marked departure from past practice. A 1998 study of prosecutions of medical personnel for their pain management of dying patients found that *none* of the investigations were initiated by the state, but were instead the result of "informants" bringing cases to the authorities' attention. *See* Ann Alpers, *Criminal Act or Palliative Care?*, 26 J. L. Med. & Ethics 308, 315 (1998).

[35] *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), is not to the contrary. The Court held that the CSA should not be read with an implicit medical necessity defense for the distribution of a Schedule I drug. The case is inapposite for a variety of re sons, including that a distributor rather than a physician or patient sought to use the defense and that the drug at issue was a Schedule I drug, which by definition has *no* currently accepted medical use. *See id.* at 499-501. (Stevens, J., concurring).

[36] *See* Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain*, 26 J. L. Med. & Ethics 332, 340 (1997).

[37] *See* Marshall B. Kapp, *Treating Medical Charts Near the End of Life*, 28 U. Tol. L. Rev. 521, 523 (1997).

patient is undertreated."[38] Research suggests that physician attitudes remain strongly biased toward risk reduction and away from pain alleviation:[39]

> [H]owever weak the factual foundations, the anxieties felt by physicians and other health care providers about potential criminal, civil, and/or regulatory liabilities are real and palpable influences on the quality and humanity of medical care actually provided to the most vulnerable patients. This is true even for those physicians who understand that their own legal exposure is minimal.[40]

In fact, a 1991 HHS report found that "[p]hysicians' fear of investigation remains a leading cause of pain undertreatment."[41] The Directive exacerbates such concerns.

In upholding the right of physicians to advise their patients on the medicinal use of marijuana, the Ninth Circuit similarly recognized the essential dilemma posed by federal intrusion into the regulation of medical treatment. *See Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002). Judge Kozinski emphasized that, while doctors "derive no direct

[38] *See* Rima J. Oken, Note, *Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917, 1944 (2002).

[39] *See* Martino, *supra*, at 332; *see also* Alpers, *supra*, at 308; J. David Haddox & Gerald M. Aronoff, Commentary, *The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain*, 26 J. L. Med. & Ethics 350, 351 (1998); Sandra H. Johnson, *Disciplinary Actions and Pain Relief*, 24 J. Law, Med. & Ethics 319-27 (1996); Michael J. Reynolds, Note, *Morphine or Malpractice*, 15 St. John's J. Legal Comment. 79, 83 (2000) (citing C. Stratton Hill, Jr., *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287, 289-92 (1996)).

[40] Kapp, *supra*, at 545.

[41] Oken, *supra*, at 1944.

benefit" from recommending marijuana use to patients "other than the satisfaction of doing their jobs well[,] . . . the *burden* of the federal policy the district court enjoined falls directly and personally on the doctors." *Id.* at 639 (Kozinski, J., concurring). Likewise, in the present case, the AG has imposed a penalty on physicians—whose only interest is their patients' well-being—to prevent patients from ending their suffering in a less painful, less prolonged manner.

Second, if the AG can unilaterally define legitimate medical practice, there is no logical basis for assuming that this power could not be extended *ad infinitum*. The AG has not advanced any limiting principle: Under its interpretation of the CSA, the AG is empowered to determine the legitimacy of any medical practice involving controlled drugs, in effect creating a new medical regulatory agency, and regulating *any* practice of medicine that involves *any* product covered by the CSA. This potentially vast authority to reach deep into the medical community has understandably concerned physicians.

Third, the Directive glosses over the significant medical issues involved in palliative care. The Directive purports to create a distinction between the "proper" distribution of pain medication and the "improper" use of medicine to hasten death. Unfortunately, the Directive's distinction is one without a difference. The practice of medicine sometimes entails the application of the doctrine of "double effect," which acknowledges the value of treating the severe pain of the terminally ill even when it is known that a consequence of that treatment may be the hastening of death.[42] As this Court noted in *Vacco v. Quill*, "[j]ust as a State may prohibit assisting suicide while permitting patients to refuse unwanted treatment, it may permit palliative care related to that refusal, which may have the foreseen but

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[42] *See* Howard Brody, *Physician-Assisted Suicide in the Courts*, 82 Minn. L. Rev. 939, 943-950 (1998).

unintended 'double effect' of hastening the patient's death." 511 U.S. at 807 n.11. In *Glucksberg*, Justice Stevens further noted that even though the American Medical Association has adopted a policy against euthanasia, it "unequivocally endorses the practice of terminal sedation—the administration of sufficient dosages of pain-killing medication to terminally ill patients to protect them from excruciating pain even when it is clear that the time of death will be advanced." *Glucksberg*, 521 U.S. at 751 (Stevens, J., concurring).[43] This widely embraced doctrine is too complex to be adequately figured into the enforcement of the CSA.[44]

Ignoring this difficulty, the Directive purports to have DEA agents second-guess physicians in an area where pain relief and death are inextricably joined. One expert has noted that the effect of the Directive will be that DEA agents "with absolutely no experience in end-of-life care will be determining if large doses of medication physicians sometimes prescribe[] to treat terminally ill patients are used with the intent of hastening death or relieving pain." Jerome Groopman, Harvard Medical School, *Separating Death from Agony*, N.Y. Times, Nov. 9, 2001, at A27.

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[43] *See also* Margaret P. Miller, *Bootstrapping Down a Slippery Slope in the Second and Ninth Circuits*, 30 Creighton L. Rev. 833, 855 (1997) ("Although some drug therapies have the 'double effect' of providing pain relief, while simultaneously hastening death, the value of the pain relief is such that the American Medical Association permits such therapy, despite its detrimental effects.").

[44] Timothy E. Quill et al., *The Rule of Double Effect*, 337 N. Engl. J. Med. 1768 (1997). In *Glucksberg*, Justice Stevens recognized the difficulty of distinguishing intent as a practical matter when, speaking of the distinction between the withdrawal of life support and assisted suicide, he noted that there might not be "a significant difference between the intent of the physicians" in these two situations. *Glucksberg*, 521 U.S. at 750.

CONCLUSION

The Directive ignores the text of the CSA and flouts deep-rooted principles of federalism. It threatens physicians and states with the loss of their long-respected right to determine the appropriate methods of medical practice and casts a pall over palliative care as physicians simply undertreat pain so as to avoid scrutiny.

The State of Oregon and people and physicians around the country have struggled in the wake of *Glucksberg* to balance competing medical, moral and public policy concerns about physician-assisted death and pain management for terminally ill individuals. They have been making progress. We therefore respectfully request the Court to affirm the decision of the Ninth Circuit.

Respectfully Submitted,

ANAND AGNESHWAR
VIJAY BALIGA
ARNOLD & PORTER LLP
399 Park Avenue
New York, New York 10022
(212)715-1000

GEOFFREY J. MICHAEL
Counsel of Record
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, District of Columbia 20004
(202)942-5000

Attorneys for *Amici Curiae*

Dated: July 18, 2005.

ADDENDUM: INDIVIDUAL AMICI

Bry Benjamin, MD, Board certified in Internal Medicine; Assistant Attending Physician, New York Presbyterian Hospital; Clinical Assistant Professor of Medicine, Weill Medical College, Cornell University; Diplomate in Geriatric Medicine, American Board of Internal Medicine; Board Member, Compassion in Dying of New York; Board Member, New York Citizens Committee on Health Care Decisions; Member, Medical and High Tech Advisory Committee of Visiting Nurse Association. Attending Physician, Manhattan Eye, Ear and Throat Hospital and Beth Israel Hospital, North Division; Member, Committee on Public Health and Managed Care Task Force and Committee on Government Affairs, New York County Medical Society; Member, Advisory Board, David Rogers Health Colloquium, New York Hospital, Cornell Medical Center; Fellow, American College of Physicians and New York Academy of Medicine.

Robert V. Brody, MD, Clinical Professor of Medicine and Family & Community Medicine, University of California-San Francisco; Chief, Pain Consultation Clinic; Chair, Ethics Committee, San Francisco General Hospital.

Howard A. Freed, MD, Clinical Professor of Emergency Medicine at Georgetown University School of Medicine; Attending Physician, Howard University Hospital; Clinical Professor of Medicine Howard University School of Medicine.

Myron Goldsmith, MD, Medical Oncologist; Founding Member and Former Executive Director, Development for the City of Hope Oncology Network; Board of Directors,

CoHON & City of Hope Management Services Organization.

Howard A. Grossman, MD, Executive Director, American Academy of HIV Medicine. Associate Attending Physician at St. Luke's-Roosevelt Hospital Center in Manhattan; Assistant Clinical Professor of Medicine at Columbia University, College of Physicians and Surgeons. Board of Directors: Visual AIDS, working with artists with HIV and using art to educate about HIV; The New York Chapter of Compassion in Dying, a national group dedicated to helping patients with end-of-life issues, especially around pain control; the Organization of HIV Healthcare Providers, a PAC organized to work on various issues of interest to people with HIV and their practitioners; and the Honorary Board of Love Heals/The Allison Gertz Foundation. Former: Board Chair for the New York State Chapter of AAHIVM and Chairman of the Public Policy Committee and Chairman of the Ethics Committee.

Ann Jackson, MBA, Executive Director and Chief Executive Officer, Oregon Hospice Association (since 1988). Author of numerous publications regarding hospice and end of life care, including the hastening death. Member of Task Force to Improve Care for Terminally Ill Oregonians; Physicians Orders for Life Sustaining Treatment Task Force; Oregon Partnership for Cancer Control; Oregon Heart Disease and Stroke Coordinating Council; Oregon Pioneer Elders Network; Community Health Charities of Oregon; Scleroderma Foundation Oregon Chapter; National Hospice and Palliative Care Organization (National Quality Advisory Council, State Issues Committee, Standards Committee, and State Hospice Executives Roundtable); Dean's Advisory Board of the Geo. H. Atkinson Graduate School of Management at Willamette University.

Pieter R. A. Kark, MD, FAAN, FACP, Member, Committee on Bioethical Issues, Medical Society of the State of New York; Formerly: Practitioner of neurology in Syracuse, New York; Facilitator, AMA/Robert W. Johnson Foundation course Education for Physicians on End-of-Life Care; Lecturer, Program in Medical Humanities, SUNY Health Science Center in Syracuse and Preceptor, Medical Humanities/Medical Ethics Course to Medical Students at SUNY Upstate Medical School in Syracuse; Health Care and Public Policy Committee, New York State Chapter of the American College of Physicians/American Society for Internal Medicine.

C. Ronald Koons, MD, FACP, Chair, Medical Ethics Committee, University of California-Irvine.

Cavin P. Leeman, MD, Clinical Professor of Psychiatry and Faculty Associate, Division of Humanities in Medicine SUNY Downstate Medical Center, Brooklyn, N.Y.; Board-certified in Psychiatry with special interest and expertise in medical ethics and end-of-life care; Distinguished Life Fellow, American Psychiatric Association; Fellow, Academy of Psychosomatic Medicine; Fellow, New York Academy of Medicine; Member Emeritus, American College of Psychiatrists; Member, American Society for Bioethics and Humanities.

Charles F. McKhann, MD, Professor of General Surgery and Surgical Oncology, Yale University School of Medicine; Member, Editorial Board, Cancer Research; Member, Yale New Haven Hospital Cancer Committee; Author of numerous publications regarding cancer research and

treatment, Author, "A Time to Die, The Place for Physician Assistance," Yale University Press 1999.

Paul V. O'Donnell, MD, PhD, Associate Member, Fred Hutchinson Cancer Research Center; Associate Professor of Medicine, University of Washington; Attending Physician, Seattle Cancer Care Alliance, Seattle, WA; University of Washington Medical Center, Seattle, WA

Russell Portenoy, MD, Chairman, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center; Professor of Neurology and Anesthesiology, Albert Einstein College of Medicine; Editor-in-Chief, Journal of Pain and Symptom Management. Dr. Portenoy is one of the most widely published experts on pain and palliative care.

Peter Rogatz, MD, MPH, Founding Board Member, Compassion & Choices of New York; Member, Ethics Committee of Hospice Care Network New York; Member, Bioethical Issues, Aging and Nursing Homes, and Home Care and Hospice Committees of the Medical Society of the State of New York; Board Certified in Preventive Medicine; Former Deputy Director, Montefiore Medical Center; Former Director, Long Island Jewish Medical Center; Former Professor, Preventive Medicine at State University of NY at Stony Brook; and Former Vice President for Medical Affairs and Medical Director, Hospice Program, of the Visiting Nurse Service of NY.

Bernard Shore, MD, Medical Director, Jewish Home of Rochester; Clinical Associate Professor in Medicine, Family Medicine, and Psychiatry, University of Rochester School of Medicine and Dentistry.

Bernard Sussman, MD, Faculty Member, University of Rochester School of Medicine; Member, the Palliative Care Service of Strong Memorial Hospital, University of Rochester Medical Center.

22

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Supreme Court of the United States

ALBERTO R. GONZALES, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF MEMBERS OF THE OREGON CONGRESSIONAL DELEGATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

WILLIAM R. STEIN
Counsel of Record
ERIC S. PARNES
HUGHES HUBBARD & REED LLP
1775 I Street, N.W.
Washington, D.C. 20006-2401
(202) 721-4600

Counsel for Amici Curiae

195503

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
INTEREST OF THE *AMICI CURIAE*	1
SUMMARY OF ARGUMENT	3
ARGUMENT	3
I. The Attorney General Has Acted Outside The Scope Of The Power Delegated By Congress In The CSA	3
A. As Originally Enacted, The CSA Protected The Historical Prerogative Of States To Regulate The Practice Of Medicine And Denied The Attorney General Any Discretion To Regulate Medical Use Of Approved Controlled Substances	5
B. The 1984 Amendments To The CSA Did Not Expand The Attorney General's Limited Statutory Authority	11
II. Congress Has Manifested Its Understanding That The Attorney General Lacks Authority To Preempt State Regulation Of Physician-Assisted Suicide	18
A. Congress Has Recognized That The CSA Does Not Authorize Federal Preemption Of State Law Regarding The Legitimacy Of Physician-Assisted Suicide	18

Contents

	Page
B. Congress Has Recognized That Federal Law Leaves The Regulation Of Physician-Assisted Suicide To The States	21
III. The Regulation of Physician-Assisted Suicide Is Within The Core Of The States' Power And Competence	23
A. Regulation Of The Practice Of Medicine And Related Issues Of Medical Ethics Has Traditionally Fallen To The States	23
B. This Court Has Recognized That Resolution Of The Difficult Moral, Practical, And Ethical Questions Associated With Physician-Assisted Suicide Is Appropriately Entrusted To The States	26
CONCLUSION	27

TABLE OF CITED AUTHORITIES

	Page
U.S. Cases:	
Barsky v. Bd. Of Regents, 347 U.S. 442 (1954) ...	24
Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988)	4
Brotherhood of Locomotive Engineers v. Atchison, Topeka & Santa Fe Railroad Co., 516 U.S. 152 (1996)	17
Business Roundtable v. S.E.C., 905 F.2d 406 (D.C. Cir. 1990)	14
Circuit City Stores, Inc. v. Adams, 532 U.S. 105 (2001)	17
Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975)	23
Gonzales v. Raich, 125 S.Ct. 2195 (2005)	6
Hillsborough County v. Automated Med. Labs, 471 U.S. 707 (1985)	23-24
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)	20
NAACP v. Federal Power Comm'n, 425 U.S. 662 (1976)	14
New State Ice Co. v. Liebman, 285 U.S. 262 (1932)	26

Cited Authorities

Page

New York Tel. Co. v. New York State Dep't of Labor, 440 U.S. 519 (1979) 19

Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004) 16

Pegram v. Herdrich, 530 U.S. 211 (2000) 23

United States v. Hunter, 101 F.3d 82 (9th Cir. 1996) 20

United States v. Moore, 423 U.S. 122 (1975) 10, 11

Washington v. Glucksberg, 521 U.S. 702 (1997) .. 19, 26, 27

Watson v. Maryland, 218 U.S. 173 (1910) 23

Statutes and Regulations:

10 U.S.C. § 1094 (2000) 24

21 U.S.C. § 396 (2000) 24

21 U.S.C. §§ 800 *et seq.* (2000) ..... *passim*

42 U.S.C. § 263 (2000) 24

42 U.S.C. § 1395 (2000) 21, 24

Assisted Suicide Funding Restriction Act, Pub. L. No. 105-12, 111 Stat. 23 (1997) 21

Cited Authorities

Page

Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) 3, 5, 6, 7

Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, 98 Stat. 1837 (1984) 12

Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 (1974) 7

Or. Rev. Stat. §§ 127.800-127.995 (2001) 1

21 C.F.R. 1306.04 (2004) 4, 11

Miscellaneous:

AMA, *Code of Ethics* § E-2.06, *available at* http://www.ama-assn.org/ama/pub/category/8419.html 25

AMA, *Frequently Asked Questions In Ethics*, http://www.ama-assn.org/ama/pub/category/5105.html 25

California Compassionate Choice Act, 2005-06 Cal. AB No. 654 (Cal. 2005) 26

Conquering Pain Act, H.R. 2188, 106th Cong. (1999) 2

15 CQ Researcher 421 (May 13, 2005) 26

Page

130 Cong. Rec. (1984):
H9680 13
S758 13

143 Cong. Rec. (1997):
H1397 22
S3249 22

Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Nov. 9, 2001) ... 4, 11

H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566 ..... *passim*

H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029 7

H.R. Rep. No. 98-1030 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182 13

H.R. Rep. No. 105-683 (1998) 19, 20

H.R. Rep. No. 106-378 (1999) 19, 20

Hugh I. Schade, M.D., Denial of Application, 60 Fed. Reg. 56,354 (Nov. 8, 1995) 11

Lethal Drug Abuse Prevention Act, H.R. 4006, 105th Cong. (1998) 18

Page

Letter from Hon. Janet Reno, Attorney General of the United States, to Hon. Henry Hyde, Chairman on the Judiciary, United States House of Representatives (June 5, 1998), *available at* http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html 20

Louis Finkelstein Institute for Social and Religious Research and HCD Research, *Poll: Majority of Doctors Support Ethics of Physician Assisted Suicide*, Business Wire (March 3, 2005) 25

Memorandum from Deputy Assistant Attorney General Sheldon Bradshaw to Hon. John Ashcroft, Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under the Drug Enforcement Administration Regulations Implementing the Controlled Substances Act (June 27, 2000), *reprinted in* 17 Issues L. & Med. 269, 271-72 (2002) 11-12

Nancy Vogel, *Oregon Law Fuels Debate on Suicide*, L.A. Times, May 24, 2005 26

Pain Relief Promotion Act, H.R. 2260, 106th Cong. (1999) 2, 18-19

S. Rep. No. 98-225, *reprinted in* 1984 U.S.C.C.A.N. 3182 ..... 12, 13, 16

S. Rep. No. 106-299 (2000) 19, 20, 21

INTEREST OF THE *AMICI CURIAE*

Amici are Members of Congress representing the people of the State of Oregon.[1] *Amicus* Ron Wyden has the honor of serving Oregon in the United States Senate. *Amici* Earl Blumenauer, Peter DeFazio, Darlene Hooley, and David Wu have the honor of serving Oregon in the United States House of Representatives. As members of Congress, *amici* are directly concerned with the need to carefully circumscribe within constitutional and statutory limits the authority of the Executive Branch to preempt the considered policy judgments made by the states and their citizens.

While serving in the United States Congress, *amici* have taken the lead in helping to defeat attempts at legislative preemption of Oregon law. Though he voted twice as a private citizen against the Oregon ballot measures that approved Oregon's Death With Dignity Act ("Dignity Act"), Or. Rev. Stat. §§ 127.800-127.995 (2001), Senator Wyden also has twice testified before the Senate Judiciary Committee, as well as once before the Senate Committee on Health, Education, Labor, and Pensions, in opposition to bills seeking amendments to the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.* (2002), that would have preempted the decision of the citizens of Oregon reflected in the Dignity Act. Similarly, Representative DeFazio—who has a masters degree in gerontology and has counseled seniors on end-of-life issues—testified before the House Judiciary Committee in opposition to the legislation seeking to overturn the Dignity Act.

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1. Consents to the filing of this *amici curiae* brief are on file with the Clerk of the Court pursuant to Rule 37(3) of the Rules of the Supreme Court of the United States. Pursuant to Rule 37(6), counsel for *amici* certifies that no counsel for a party authored this brief in whole or in part and that no person, other than *amici* or their counsel, made a monetary contribution to the preparation or submission of this brief.

Representatives DeFazio, Blumenauer, Hooley, and Wu each fought against passage of the "Pain Relief Promotion Act," H.R. 2260, 106th Cong. (1999), in order to protect from federal preemption Oregon's thoughtful approach to giving terminally-ill patients more control over difficult end-of-life issues.

Congresswoman Hooley, representing Oregon's Fifth Congressional District, despite personal opposition to the practice of physician-assisted suicide, joined her Republican colleague from Connecticut, Representative Nancy Johnson, in introducing the "Conquering Pain Act," H.R. 2188, 106th Cong. (1999), coauthored by Senator Wyden, as a substitute for the Pain Relief Promotion Act in order to improve palliative care without overturning Oregon law.

Similarly, Representative Wu, representing Oregon's First Congressional District, actively opposed the Pain Relief Promotion Act in the 106th Congress, and joined his colleagues in sending a letter to former President Clinton urging him to oppose any legislation that would overturn Oregon's law. Likewise, during the 107th Congress, he joined the Oregon delegation in requesting a meeting with President Bush and Attorney General Ashcroft before the Administration considered any action regarding Oregon's Dignity Act. Representative DeFazio joined more than fifty health and hospice related organizations to defeat attempts to overturn the Oregon law.

Because of their experience with the CSA and the policy debate about physician-assisted suicide during their time in the United States Congress, *amici* Senator and Representatives can offer a unique insight into the CSA's legislative purpose and history, into the Congressionally-drawn demarcation between the role of the states and the role of the Attorney General under the CSA, and into the proper relationship between the CSA and Oregon's Death With Dignity Act. In addition, Senator Wyden served in the United States House of Representatives at the time

of the 1984 amendments to the CSA, and thus can bring his perspective on the purpose of the 1984 amendments to an analysis of the CSA.

SUMMARY OF ARGUMENT

All parties and *amici* agree that regulation of the practice of medicine, including matters of medical ethics, has traditionally been the province of the states. Nothing in the CSA alters state primacy in this area. The statute, which was enacted for the purpose of controlling drug trafficking and abuse, does not authorize the Attorney General to preempt state law on issues regarding the ethical practice of medicine.

ARGUMENT

I. The Attorney General Has Acted Outside The Scope Of The Power Delegated By Congress In The CSA.

Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, to "deal in a comprehensive fashion with the growing menace of drug abuse in the United States." H.R. Rep. No. 91-1444 (Sept. 10, 1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567. Title II of the Act, dealing with "control and enforcement," was designated the Controlled Substances Act. *Id.* at 4569. From its inception in 1970, its amendment in 1984, and its consistent construction and application over three decades, the CSA directed the Attorney General to enforce a closed system of drug distribution and dispensing as a means of curbing drug abuse and controlling drug trafficking. Nothing in the language, history, or application of the original or amended CSA authorized the Attorney General to use his law enforcement powers to proscribe as illegitimate those medical practices that fail to conform to his moral convictions.

In an unprecedented expansion of his role under the CSA, the Attorney General in his 2001 Interpretive Rule asserted that he is authorized to prohibit physicians from prescribing drugs in accordance with the Dignity Act. *See* Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607, 56,608 (Nov. 9, 2001) (the "Interpretive Rule"). He found that authority in a DEA regulation supplying the criteria for what constitutes an effective prescription for a controlled substance under the CSA. *Id.* Promulgated in 1971, that regulation provides that a "prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. 1306.04(a) (2004). The Attorney General declared in his Interpretive Rule that he had "determined that assisted suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR 1306 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act." 66 Fed. Reg. at 56,608. Thus, thirty years after its promulgation, this heretofore unremarkable regulation has become the vehicle by which the nation's chief law-enforcement officer seeks to become arbiter of the legitimacy of medical practices, to usurp the traditional state prerogative of regulating the practice of medicine, and to derogate the outcome of Oregon's political process acting within the core of its traditional competency.

Viewed in light of the language and purpose of the statute under which it was promulgated, the 1971 regulation simply does not provide the Attorney General with the broad authority to preempt state law that he seeks. The CSA cannot sustain such a dramatic expansion of the Attorney General's limited authority under that statute. To the contrary, the terms and legislative history of the CSA demonstrate the will of Congress to respect the traditional prerogative of the states to regulate the practice of medicine. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative

agency's power to promulgate legislative regulations is limited to the authority delegated by Congress.").

A. As Originally Enacted, The CSA Protected The Historical Prerogative Of States To Regulate The Practice Of Medicine And Denied The Attorney General Any Discretion To Regulate Medical Use Of Approved Controlled Substances.

The terms and history of the CSA as originally enacted belie the claim that Congress gave the Attorney General, a law-enforcement officer, final word as to which state-sanctioned medical practices are "legitimate." The CSA was "designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs." H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. at 4589. Congress authorized the Attorney General to exercise several law enforcement functions intended to keep controlled substances from escaping the closed system and flowing to illicit channels. Congress never delegated any power or discretion to the Attorney General to make judgments about the proper medical use of controlled substances. Those matters were left to state law—which traditionally has regulated the practice of medicine—or, in specific, limited circumstances, to federal officials with expertise in medical and scientific matters.

As part of its effort to regulate drug distribution and prevent diversion to illicit channels, Congress in the CSA required that medical practitioners wishing to prescribe controlled substances register with the Attorney General. Pub. L. No. 91-513, 302(a), 84 Stat. 1236, 1253. Under the CSA as originally enacted, practitioner "registration would be as a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under state law." H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. at 4590. The Attorney

General was required to register practitioners "if they are authorized to dispense . . . controlled substances under the law of the State in which they practice." Pub. L. No. 91-513, § 303(f), 84 Stat. 1253 (1970).[2] When it enacted the CSA, therefore, Congress unquestionably intended to leave solely to the states the power to license and discipline medical practitioners regarding the use of controlled substances, and gave the Attorney General no leeway to override the state regulators' determinations or otherwise to exercise discretion regarding medical issues.[3]

To be sure, Congress in the original CSA provided for a limited federal role in medical issues relating to use of controlled substances. That federal role, however, was highly circumscribed and directly related to the core concern of the Act, *i.e.*, maintaining a closed system for distribution of potentially dangerous drugs. Further, that limited federal medical role was entrusted to federal officials with medical expertise at the Department of Health, Education and Welfare, not to federal officials with law enforcement expertise at the Department of Justice.

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2. This provision was amended in 1984. As demonstrated *infra*, at Part I.B., and contrary to the assertions of the Attorney General and various *amici*, the 1984 amendments to the CSA's registration provisions did not abandon the requirement of deference to state regulation of the practice of medicine.

3. This Court's recent decision in *Gonzales v. Raich*, 125 S. Ct. 2195 (2005), is not to the contrary. *Raich* addressed a commerce-clause challenge to the decision of Congress to prohibit the local use of locally-grown marijuana, and did not consider the Attorney General's authority under the CSA. Also, *Raich* concerned federal authority under the drug-scheduling, rather than the physician-licensing, authority conferred by the CSA. While scheduling decisions involve medical determinations, Congress in the CSA expressly entrusted those decisions to federal officials with medical expertise (or in some cases made the decision itself). *See infra* at 8.

Accordingly, the CSA vested the Secretary of Health, Education, and Welfare (now, the Secretary of Health and Human Services)—not the Attorney General—with authority over medical and scientific determinations relating to the scheduling of controlled substances. *See* 21 U.S.C. § 811(b) (2000) (determinations of the Secretary "shall be binding on the Attorney General as to such scientific and medical matters"). Likewise, Congress granted the Secretary of Health, Education, and Welfare the authority to determine national standards for the use of methadone and other narcotics in the treatment of addicts. Pub. L. No. 91-513, Tit. I, § 4, 84 Stat. 1236, 1241.

The Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124, which amended the CSA to set forth procedures governing practitioner registration to conduct addiction treatment programs, provides further evidence of the Congressional will to withhold from the Attorney General discretionary authority over medical determinations. The legislative history of the 1974 amendments demonstrates that Congress intended to "preserve . . . the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary of Health, Education and Welfare." H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3024. Congress intended that "[a]ll decisions of a medical nature are to be made by the Secretary. . . . Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General." *Id.*

As even the *amici* federal legislators who support the Attorney General recognize, "Congress never intended to displace the states as primary regulators of physicians, and the CSA was never intended to result in a wholesale nationalizing of the practice of medicine." *Amicus Curiae* Brief of Senators Rick Santorum, et al., at 19 ("Santorum Br."). Prior to the Interpretive Rule, the only attempt by the federal government to regulate the practice of medicine under the CSA dealt with

the use of narcotics in addiction treatment, which directly relates to the central purpose of the CSA. It is not surprising that Congress wanted a federal role in defining the manner in which narcotics were placed in the hands of addicts, the most likely vehicles for diversion from proper to illicit channels. Congress, however, granted this limited authority not to the Attorney General, but to "the principal health agency of the federal government." H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. at 4581. Given this statutory scheme, it is absurd to suggest that Congress implicitly vested the Attorney General with the uncabined authority to declare illegitimate state-sanctioned medical practices unrelated to the evils to which the CSA was directed. While uniform guidelines for the methods by which physicians place narcotics in the hands of addicts serve the anti-diversion goals of the CSA, a national standard regulating the medical purposes that physicians may legitimately pursue serves no such goal.

Despite this clear indication of Congressional intent to defer to the states, the Attorney General and certain *amici* insist that, even under the original CSA, the Attorney General had the authority to override a state's decisions as to the legitimacy of particular medical purposes. Two arguments are raised in support of this position, but neither holds water.

First, the Attorney General and certain *amici* insist that the federal drug-control laws that preceded the CSA "created a federal standard for determining what constitutes a legitimate medical practice," and that the CSA was intended to "clarify that *federal* standard, not to cloud that standard by overlaying potentially disparate state standards." Brief for the Petitioners at 33 ("Gov. Br.") (emphasis in original); *see also* Santorum Br. at 18-19. This argument is grounded on a gross mischaracterization of the legislative history. The Attorney General relies on the Report of the House Committee On Interstate And Foreign Commerce, but that Report in fact demonstrates that Congress deliberately *denied* federal law-

enforcement personnel discretion to make medical and scientific judgments with respect to addiction treatment. *See* H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. at 4581. The House Committee recognized that previous federal drug laws had led to the problem of prosecutors indicting practitioners for their practices in treating addiction, thereby in effect exercising discretion as to the propriety of methods used to treat addiction. *Id.* Congress specifically intended to withdraw any discretion in this area from federal prosecutors and instead to authorize the Secretary of Health, Education, and Welfare (now the Secretary of Health and Human Services) to issue guidelines for prescribing narcotics to treat addicts. *See supra* at 8-9.

The Attorney General's assertion that Congress had always intended to allow the Attorney General to define appropriate medical practice is based on partial, out-of-context quotations from the House Report. The passage in full, however, makes clear that the Committee was describing with disfavor the situation created by the Justice Department's overbroad assertion of authority under pre-1970 federal narcotics legislation in the specific area of addiction treatment.[4] Placed in context, the

4. In full, with *italics* indicating the portions the Attorney General omitted in his selective excerpt, the passage reads:

> *The Committee expects that the determinations made by the Secretary of Health, Education, and Welfare will clarify for the medical profession the conditions under which narcotic drugs may be prescribed for the medical treatment of narcotic addicts.* Although the Committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutors of what constitutes appropriate methods of professional practice. *In view of this situation, this*

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passage demonstrates that Congress sought to avoid any intervention in medical matters by prosecutors and other medically-unqualified federal law enforcement officials. H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. at 4581.

Second, the Attorney General (Gov. Br. at 31), and the legislative *amici* who support him (Santorum Br. at 10), argue that this Court's decision in *United States v. Moore*, 423 U.S. 122 (1975), recognized the Attorney General's authority to declare uniform federal standards for permissible prescriptions under the CSA. In *Moore*, however, this Court did not address the issue whether the CSA empowers the Attorney General to determine the legitimacy of particular medical purposes. Instead, the physician defendant in *Moore* had been found to be acting as a methadone pusher rather than as a physician and thus could not claim immunity from prosecution under the more severe provisions of the CSA. *Id.* at 133. To the extent that the holding depended on the existence of a federal standard for appropriate practice, the Court looked only to the "particularly clear" limits on practices relating to methadone treatment, the articulation of which the 1970 Act expressly committed to the Secretary of Health, Education, and Welfare. *Id.* at 144. Neither the Attorney General nor any of the fifteen *amici* briefs in support of his position has identified a single instance in which the federal government has based a prosecution or license revocation on a

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(Cont'd)

> *section will provide guidelines, determined by the principal health agency of the federal government, after consultation with appropriate national professional organizations. Those physicians who comply with the recommendations made by the secretary will no longer jeopardize their professional careers by accepting addicts as patients.*

H.R. Rep. 91-1444, 1970 U.S.C.C.A.N. at 4581.

finding of an illegitimate medical purpose other than conduct amounting to "pill pushing."[5]

B. The 1984 Amendments To The CSA Did Not Expand The Attorney General's Limited Statutory Authority.

Although based primarily on the Attorney General's interpretation of the phrase "legitimate medical purpose" in the 1971 regulation now found at 21 C.F.R. 1306.04(a) (2004), the Interpretive Rule also purports to rely on the 1984 amendments to the CSA to support the threat of enforcement action against physicians prescribing controlled substances pursuant to the Dignity Act.[6] *See* 66 Fed. Reg. at 56,608; *see also* Gov. Br. at 34-35. Likewise, the Attorney General invokes the 1984 amendments as support for the proposition that Congress intended to depart from its traditional deference to state regulation of medical practice. The substance and history of the

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5. *Hugh I. Schade, M.D., Denial of Application*, 60 Fed. Reg. 56,354 (Nov. 8, 1995), cited in Santorum Br. at 24 n.7, is not such a case. In that proceeding, the DEA simply found it appropriate to deny a physician's application for registration due to the physician's having been convicted in state court of involuntary manslaughter in connection with the death of a patient and having been found by the DEA to be in violation of numerous regulations concerning the keeping of controlled substances. The decision did not involve any determination of the legitimacy of physician-assisted suicide or otherwise federalize the issue of what constitutes the legitimate practice of medicine.

6. If the Attorney General's interpretation of 21 C.F.R. 1306.04 stands, practitioners acting pursuant to the Dignity Act also would potentially be subject to criminal penalties under 21 U.S.C. § 841. *See United States v. Moore*, 423 U.S. 122, 136 (1975); *see also* Memorandum from Deputy Assistant Attorney General Sheldon Bradshaw to Hon. John Ashcroft, Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under the Drug Enforcement Administration Regulations Implementing the Controlled Substances Act (June 27, 2000), *reprinted in* 17 Issues L. & Med. 269, 271-72 (2002).

1984 amendments support neither of these assertions. To the contrary, the 1984 amendments reaffirmed the Act's fundamental division of authority.

The 1984 amendments began as the "Dangerous Drug Diversion Control Act" and later were incorporated into the Comprehensive Crime Control Act of 1984. Pub. L. No. 98-473, 98 Stat. 1837 (1984). As the original bill title reflects, Congress intended the 1984 legislation to address a specific issue: the "problem of diversion of drugs of legitimate origin into the illicit market." S. Rep. No. 98-225, *reprinted in* 1984 U.S.C.C.A.N. 3192, 3442; *see also id.* at 3182, 3444. Although the CSA's original registration provisions had proven effective in "meeting the diversion problem at the manufacturer and distributor levels," Congress was concerned that "the same strong regulatory authority to maintain a 'closed' distribution chain does not exist at the practitioner level." *Id.* at 3443.

Toward the limited end of sealing leaks in the closed distribution system, Congress made applicable to the registration of practitioners a standard comparable to that already applicable to the registration of manufacturers and distributors of controlled substances. *See id.* (citing 21 U.S.C. §§ 823(a), (b), (d), (e)). Whereas the CSA had previously required the Attorney General to register any practitioner authorized to distribute controlled substances by that practitioner's state, the 1984 amendment authorized the Attorney General to deny or revoke a practitioner's DEA registration upon a finding that such registration is contrary to the "public interest." 21 U.S.C. § 824(a)(4) (added by Pub. L. No. 98-473, § 512(2), 98 Stat. 1837).

While giving the Attorney General a limited basis for denying or revoking the registration of state-licensed physicians in order to better combat illegal diversion of drugs, the 1984 amendment did not, contrary to the Attorney General's position, upset two-hundred years of tradition by vesting the nation's chief

law-enforcement officer with unfettered discretion over how medical practitioners do their work. Indeed, Congress intended that the Attorney General would be required to "continue to give deference to the opinions of the State licensing authorities." S. Rep. No. 98-225, *reprinted in* 1984 U.S.C.C.A.N. at 3449. In light of the purpose and substance of the 1984 amendments, the grant of authority to the Attorney General cannot be read as an open-ended invitation to block as "illegitimate" state-sanctioned medical practices of which he disapproves.

First, in the 1984 amendments, Congress expanded the authority of the Attorney General with respect to practitioner registration for a single purpose: to strengthen federal controls against diversion of controlled substances to illicit channels. *See, e.g.*, 130 Cong. Rec. H9680 (daily ed. Sept. 18, 1984) ("The most serious diversion problem today exists at the retail level. State policing of these activities, as well as peer review within the profession, have not been adequate control measures."); H.R. Rep. No. 98-1030 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3443 (the "strong regulatory authority to maintain a 'closed' distribution system does not exist at the practitioner level"); 130 Cong. Rec. S758 (daily ed. Feb 2, 1984) (statement of Senator Strom Thurmond) (arguing that the amendment was appropriate given that "80 to 90 percent of current diversion of drugs into illicit markets takes place" at the practitioner level); *see also* Santorum Br. at 13 ("The theme of needing to better control the distribution of controlled substances through physicians by shoring up weaknesses at the state level pervades the legislative history [of the 1984 amendments].").

The 1984 amendments do not support the Attorney General's authority to make registration determinations based on a definition of the "public interest" that has no relationship to that Congressional goal. The "public interest" provision was meant to strengthen federal enforcement of the closed system, not to authorize federal regulation of the practice of medicine.

As with any regulatory statute, the term "public interest" must be construed in light of the statutory purpose. *See, e.g.*, *NAACP v. Federal Power Comm'n*, 425 U.S. 662, 669 (1976) ("The use of the words 'public interest' in a regulatory statute . . . take meaning from the purposes of the regulatory legislation."); *see also Business Roundtable v. S.E.C.*, 905 F.2d 406, 413-14 (D.C. Cir. 1990) (rejecting SEC's attempt to invoke statute's "public interest" mandate to assert authority in an area of "firmly established" state jurisdiction and noting that affirming this "advance into an area not contemplated by Congress would circumvent the legislative process that is virtually the sole protection for state interests").

Second, the term "public interest" does not stand alone in the amended CSA. Instead, section 824(a)(4) allows the Attorney General to revoke or suspend a registrant upon a finding that the registrant "has committed such acts as would render his registration *under section 823* of this title inconsistent with the public interest *as determined under such section.*" 21 U.S.C. § 824(a)(4) (emphasis added). The provision on which the Attorney General relies cannot be read apart from the provision on which it explicitly depends. It is under 21 U.S.C. § 823 that the meaning of "inconsistent with the public interest" is determined.

Section 823 provides an exclusive list of the factors that the Attorney General may consider in determining the "public interest":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). Nothing about these five factors—and certainly nothing in the legislative history of the 1984 amendments—suggests that Congress intended to upset the fundamental principle it had established in 1970: that the regulation of medical practice be left to the states other than as necessary to prevent diversion of controlled substances into illicit markets, and that any federal intrusion into medical and scientific matters must be specifically authorized, delegated to federal health officials, and off-limits for the Attorney General.

The Attorney General does not purport to rely on the first three factors, and for good reason. The first factor reaffirms the primacy of state regulators in determining the eligibility of practitioners for CSA registration. As the 1984 Senate Report made clear, the amended registration provisions require that the Attorney General "continue to give deference to the opinions of state licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applicants." S. Rep. No. 98-225, *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449.[7] This requirement of deference to state officials

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7. As the Ninth Circuit found, "[i]t is undisputed that the Attorney General made no effort to solicit input from the State of Oregon before issuing his Directive, notwithstanding an express promise to do so by his subordinates." *Oregon v. Ashcroft*, 368 F.3d 1118, 1129 (9th Cir. 2004).

only serves to highlight the fallacy in the Attorney General's suggestion (Gov. Br. at 35) that the CSA prescribes exclusively federal standards for regulating use of controlled substances by medical practitioners. Nothing in the 1984 amendments or their legislative history suggests that such national uniformity was one of Congress's goals.

The second and third factors, meanwhile, are objective considerations that have nothing to do with the scientific or ethical legitimacy of particular medical purposes.

The Attorney General is thus left with the fourth and fifth factors. As to factor four, whether a physician who prescribes a controlled substance to assist suicide in a manner consistent with Oregon law fails to comply with "applicable . . . Federal . . . laws relating to controlled substances," 21 U.S.C. § 823(f)(4), begs the question currently before the Court.

The fifth factor permits the Attorney General to consider "[s]uch other conduct which may threaten the public health and safety." 21 U.S.C. § 823(f)(5). The term "public health and safety," however, does not provide the Attorney General with discretion to define the legitimate practice of medicine. The phrase must be construed in light of the purpose and structure of the CSA itself, which is directed toward preventing the diversion of controlled substances to illicit channels and which reserves medical determinations to the states and (in limited instances) to federal health officials.[8] It would be odd, indeed, for Congress to have departed so radically from the basic structure of the CSA in such a "back door" manner.

As this Court has observed of similar statutory provisions, section 823(f)(5) "calls for the application of the maxim *ejusdem*

8. *See Brotherhood of Locomotive Engineers v. Atchison, Topeka & Santa Fe Railroad Co.*, 516 U.S. 152, 157 (1996) (recognizing that, where a statute's objective is apparent, statutory terms "must be understood in accord with that objective").

generis, the statutory canon that '[w]here general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.'" *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114-15 (2001) (quoting 2A N. Singer, *Sutherland on Statutes and Statutory Construction* § 47.17 (1991)). None of the four enumerated factors preceding section 823(f)(5) involves anything remotely similar to a major policy determination defining the legitimate practice of medicine based on considerations of morality, or a wholesale preemption of matters that are the historical province of the states.

In sum, the 1984 amendments to the CSA's registration provisions did not alter the goals or basic structure of the Act.[9] The amendments enhanced the federal government's authority to act to maintain the closed system for distribution of controlled substances. They did not, however, effect the sea change in federal policy towards the regulation of the practice of medicine that the Attorney General urges.[10]

9. Insistence by *amici* federal legislators that, in the event of affirmance in this case, "Oregon will merely have carved out of the CSA a specific purpose for controlled substances (i.e., assisting suicides) that is governed solely by state law," Santorum Br. at 21, misses the mark. Regulation of particular medical purposes has never been within the ambit of the CSA. Affirmance would thus restore the status quo in which the Attorney General lacked discretion to carve out specific purposes from those for which a prescription could be written. Under that status quo, state standards were pivotal—rather than anathema—to the enforcement of the CSA's registration provisions.

10. The strong bipartisan support for the amendments identified by *amici*, *see* Santorum Br. at 15, is not consistent with the theory that the 1984 amendments were intended to radically alter the balance of state and federal power in the area of regulation of medical practice.

II. Congress Has Manifested Its Understanding That The Attorney General Lacks Authority To Preempt State Regulation Of Physician-Assisted Suicide.

Since the enactment of Oregon's Dignity Act, Congress has three times considered bills dealing with assisted suicide. The Congressional proponents and opponents of these legislative efforts understood that federal authority under the CSA did not reach physician-assisted suicide and that, at a minimum, new federal legislation would be required to defeat the Dignity Act.

A. Congress Has Recognized That The CSA Does Not Authorize Federal Preemption Of State Law Regarding The Legitimacy Of Physician-Assisted Suicide.

In 1998, opponents of the Dignity Act introduced H.R. 4006, entitled the "Lethal Drug Abuse Prevention Act," 105th Cong. (1998), which would have authorized the Attorney General to suspend or revoke the registration of a physician prescribing lethal doses of drugs to terminally ill patients to assist suicide, even if authorized by state law. The bill failed. In 1999, the opponents made another attempt at preempting the Oregon law in H.R. 2260, the "Pain Relief Promotion Act," 106th Cong. (1999), which also failed.[11] Implicit in these attempts is the recognition that the CSA does not preempt, or authorize the Attorney General to preempt, state law in this area.

While failed legislative proposals generally are accorded limited weight in statutory interpretation, in appropriate contexts

11. Both proponents and opponents of the bills acknowledged that the amendments targeted the Dignity Act. *See, e.g.*, S. Rep. No. 106-299, at 7, 18 (2000) (Senate Judiciary Committee Report on H.R. 2260); *id.* at 54-55 (minority views); H.R. Rep. No. 106-378, at 5 (1999) (House Judiciary Committee Report on H.R. 2260); H.R. Rep. No. 105-683, at 6 (1998) (House Judiciary Committee Report on H.R. 4006).

rejected attempts at amending a statute may provide valuable guidance in determining the scope of the unamended legislation. *See New York Tel. Co. v. New York State Dep't of Labor*, 440 U.S. 519, 544-45, 544 n.44 (1979) (finding that two instances in which Congress considered and failed to approve attempts to expressly preempt state power indicated lack of preemption). This is such a case, because the context in which Congress considered these failed bills is particularly helpful in delineating the scope of the Attorney General's authority under the CSA in its present form.

First, the amendments to the CSA were proposed in the wake of this Court's observation in *Washington v. Glucksberg* that "Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." 521 U.S. 702, 735 (1997). In light of this observation, the sponsors of the failed bills recognized that this debate would continue in the states unless Congress stepped in to amend the CSA to preempt the Oregon, and any similar state, law. The CSA, however, was not so amended.

Second, Congress failed to amend the CSA despite Attorney General Reno's 1998 interpretation of the CSA as *not* authorizing preemption of state law on physician-assisted suicide. *Cf. United States v. Hunter*, 101 F.3d 82, 85 (9th Cir. 1996) (presuming that Congress is aware of, and acquiesces to, existing interpretations of its laws when it subsequently enacts amendments). After "thorough and careful review of the issue," Attorney General Reno explained her conclusion that "[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." Letter from Hon. Janet Reno, Attorney General of the United States, to Hon. Henry Hyde, Chairman on the Judiciary, United States House of Representatives (June

5, 1998), *available at* http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html. At virtually every stage in Congress's consideration of the two bills, both proponents and opponents mentioned Attorney General Reno's interpretation.[12] The failure of these attempts to override Attorney General Reno's interpretation of the CSA, while lacking the force of an affirmative legislative enactment, should carry great weight in assessing whether the CSA in its present form empowers the current Attorney General to preempt state law.

When asked to interpret federal statutes as preempting state law, this Court has held that courts should "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Given the lack of any evidence that Congress ever intended the CSA to substantially preempt state regulation of the practice of medicine, Congress's recent refusals to "eviscerate the states' well-established power to regulate medical practices," S. Rep. No. 106-299, at 61 (Senate Judiciary Committee minority views on H.R. 2260), are significant.

B. Congress Has Recognized That Federal Law Leaves The Regulation Of Physician-Assisted Suicide To The States.

In 1997, Congress passed the Assisted Suicide Funding Restriction Act ("Funding Act"), Pub. L. No. 105-12, 111 Stat. 23, which prohibits the use of federal funds in assisted suicide. *Amici* refer to the Funding Act as evidence that "the position of the federal government has consistently been that it will not

12. *See, e.g.*, S. Rep. No. 106-299, at 12, 42 (2000) (Senate Judiciary Committee Report on H.R. 2260); *id.* at 52-53 (minority views); H.R. Rep. No. 106-378, at 6 (1999) (House Judiciary Committee Report on H.R. 2260); H.R. Rep. No. 105-683, at 6 (1998) (House Judiciary Committee Report on H.R. 4006).

facilitate suicide." Santorum Br. at 25. This proposition, however, is beside the point.[13] The decision not to provide federal funds for physician-assisted suicide does not imply an authorization for federal officials to prohibit, or to preempt state laws authorizing and regulating, physician-assisted suicide. Indeed, when Congress enacted the Funding Act, it did so with the explicit understanding that the power to regulate assisted suicide remained with the states.

Then-Senator Ashcroft, speaking as a cosponsor of the Senate version of the bill, explained that the legislation would alter only allocation of federal funding:

> [The bill] *does not in any way forbid a State to legalize assisted suicide or even to provide its own funds for assisted suicide*. It simply says Federal resources are not to be used to promote or conduct assisted suicides. After passage of this bill, *States might choose to legalize or fund assisted suicide*, but they would not be able to draw on Federal resources normally drawn upon in joint efforts between the State and the Federal Government for the provision of health services.

143 Cong. Rec. S3249, S3250 (1997) (emphasis added); *see also* 143 Cong. Rec. H1397, H1402 (1997) (statement of Rep. Bilirakis). Thus, at the time of the Funding Act, Congress understood that federal law—which, of course, included the CSA—left to the states the policy decision whether to permit physician-assisted suicide.

13. The authority upon which *amici* relies—a Medicare Benefit Policy Manual—is particularly unavailing as support for a claim of federal policy antagonistic to state law. The Medicare statute provides that "[n]othing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395 (2000).

Far from demonstrating congressional understanding that physician-assisted suicide was inconsistent with federal law, the enactment of the Funding Act demonstrates Congress's recognition that state legislatures might choose to authorize assisted suicide. Otherwise, there would be no need to prohibit use of federal funds. The original sponsor of the bill in the House, Representative Ralph Hall, explained: "If assisted suicide is legalized by the Supreme Court or in any individual State, all it would take [for federal funds to be used] is for one district court judge to rule that assisted suicide fits under the State's Medicare guidelines." 143 Cong. Rec. H1397, H1403 (1997). This concern was echoed verbatim by a cosponsor of the Senate bill. 143 Cong. Rec. S3249, S3258 (1997) (statement of Sen. Nickles). The Funding Act thus demonstrates the Congressional recognition that states could and might legalize physician-assisted suicide and that, absent federal legislation, the federal government might be forced to fund the practice.

III. The Regulation Of Physician-Assisted Suicide Is Within The Core Of The States' Power And Competence.

The absence of authorization in the CSA for federal officials to regulate physician-assisted suicide is not a coincidence. Policy decisions respecting physician-assisted suicide sit at the crossroads of moral judgment and medical regulation. Tradition and constitutional doctrine recognize that decisions in these areas are properly entrusted to the states.

A. Regulation Of The Practice Of Medicine And Related Issues Of Medical Ethics Has Traditionally Fallen To The States.

As this Court has recognized, "States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests, they have broad power to establish

standards for licensing practitioners and regulating the practice of professions." *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975). The compelling interest that each state has in regulating professionals operating within its borders has particular force in the field of medicine, where the conduct of professionals relates directly to the core of state police power—the public health. *See Watson v. Maryland*, 218 U.S. 173, 176 (1910) ("There is perhaps no profession more properly open to [state] regulation than that which embraces the practitioners of medicine.").

The uniquely strong interest of states in the regulation of the practice of medicine is consistent with this Court's frequent recognition that such regulation has traditionally been the province of the states. *See Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) (health care is "a subject of traditional state regulation"); *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 719 (1985) ("the regulation of health and safety matters is primarily, and historically, a matter of local concern"); *Barsky v. Bd. Of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there."). Congress has similarly deferred to the traditional primacy of state regulation of medicine by providing in several statutes pertaining to medical matters that nothing in those statutes should be construed to authorize federal officials "to exercise supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395 (2000) (Medicare); *see also* 42 U.S.C. § 263a-2(i)(1) (2000) (Fertility Success Rate Certification Act of 1992); 21 U.S.C. § 396 (2000) (Food and Drug Administration Modernization Act of 1997); 21 U.S.C. § 823(g)(2)(H)(i) (2000) (Drug Addiction Treatment Act of 2000). So strong is the Congressional recognition of the centrality of state regulation in this area that Congress requires physicians serving in the United States military to subject themselves to state licensing regimes. 10 U.S.C. § 1094 (2000). Even *amici* writing in support

of the Attorney General have been forced to acknowledge that regulation of the practice of medicine "had always been considered primarily a state responsibility." Santorum Br. at 18.

The Attorney General, however, seeks to evade the issue of which entity has traditionally been empowered to make decisions with respect to the appropriateness of particular medical practices. Instead of addressing this issue, the Attorney General attempts to reframe the question as whether a particular medical practice has traditionally been authorized by states. *See* Gov. Br. at 39. So framed, the question lacks meaningful content. The power to authorize only medical practices that have been traditionally authorized is no power at all. This approach, moreover, would freeze medical practice as it has existed at some point in the past, and could jeopardize the advancement of medicine through the use of initially controversial practices.

Similarly, the attempt by the Attorney General and certain *amici* to characterize the Dignity Act as inconsistent with a national consensus on physician-assisted suicide is both inaccurate and inapposite. To begin, statements of ethical policy by the American Medical Association—of which approximately 30% of physicians are members[14]—and similar organizations cannot be treated as establishing a national medical consensus against physician-assisted suicide.[15] In fact, a recent national

14. *See* AMA, *Frequently Asked Questions In Ethics*, http://www.ama-assn.org/ama/pub/category/5105.html.

15. The Attorney General is quite selective in his reliance on the AMA position. The AMA Code of Ethics also prohibits physician participation in legally authorized executions, including by administering or overseeing lethal injection. AMA, *Code of Ethics* § E-2.06, *available at* http://www.ama-assn.org/ama/pub/category/8419. html. Despite the existence of identical authority in support of a supposed "national" consensus, the Attorney General has not invoked the CSA to declare such participation contrary to the public interest as he has with respect to physician-assisted suicide. Nor would he agree that the AMA position represents a national consensus on the illegitimacy of execution by lethal injection.

survey of physicians reveals that 71% of physicians support the legalization of physician-assisted suicide, at least under some circumstances.[16] Another recent national poll of the general public indicates that, far from reflecting a radical departure from national norms, authorizing doctors to participate in physician-assisted suicide for terminally ill patients is consistent with the policy preference of nearly three-quarters of the public. *See* 15 CQ Researcher 18, at 428 (May 13, 2005).[17] Reflective of these evolving views on this issue, the California legislature is currently debating a bill virtually identical to Oregon's Dignity Act. *See* California Compassionate Choice Act, 2005-06 Cal. AB No. 654 (Cal. 2005); Nancy Vogel, *Oregon Law Fuels Debate on Suicide*, L.A. Times, May 24, 2005, at A1. The question is being debated in other states as well. *Id.*

In any event, even if a strong national consensus against physician-assisted suicide did exist—and it clearly does not—the opinions of the rest of the country have nothing to do with whether each state has the presumptive authority to reach its own decision. That is, after all, the very point—and the genius—of our federal system.

16. The survey was conducted by the Louis Finklestein Institute for Social and Religious Research and HCD Research. A plurality (41%) of physicians endorse legalization of physician-assisted suicide under a wide range of circumstances, and another 30% support legalization in "a few cases." *Poll: Majority of Doctors Support Ethics of Physician Assisted Suicide*, Business Wire (Mar. 3, 2005).

17. This Gallup poll, too, reflects evolving attitudes toward the issue. In 1950, only 26% of Americans supported physician-assisted suicide for terminally-ill patients; in 2003, 72% of Americans voiced support.

B. This Court Has Recognized That Resolution Of The Difficult Moral, Practical, And Ethical Questions Associated With Physician-Assisted Suicide Is Appropriately Entrusted To The States.

A mere eight years ago, this Court acknowledged that the difficult questions surrounding physician-assisted suicide could not easily be resolved. "Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." *Washington v. Glucksberg*, 521 U.S. 702, 735 (1997).

As Justice Brandeis famously observed in his dissent in *New State Ice Co. v. Liebman*, 285 U.S. 262, 311 (1932), "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *See Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring) ("States are presently undertaking extensive and serious evaluation of physician assisted suicide and other related issues. In such circumstances, 'the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance.'" (quoting *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 292 (1990) (O'Connor, J., concurring))).

As the current debate in California and debates in other states throughout the country make clear, the wisdom of authorizing physicians to assist terminally-ill patients in hastening their deaths is a matter on which reasonable minds can and do differ. The Attorney General should not be permitted to deprive the people of Oregon and the nation the opportunity to benefit from the ultimate outcome of the "earnest and profound debate" in which they are engaged.

CONCLUSION

Amici urge this Court to affirm the decision below.

Respectfully submitted,

WILLIAM R. STEIN
Counsel of Record
ERIC S. PARNES
HUGHES HUBBARD & REED LLP
1775 I Street, N.W.
Washington, D.C. 20006-2401
(202) 721-4600

Counsel for Amici Curiae

23

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IN THE

Supreme Court of United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

STATE OF OREGON, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR THE CATO INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

MARK K. MOLLER
THE CATO INSTITUTE
1000 Massachusetts Ave., N.W.
Washington, D.C. 20001
(202) 842-0200

PAMELA HARRIS
(Counsel of Record)
GARRETT W. WOTKYNS
ARTHUR W.S. DUFF
LAURA DE JAAGER*
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
(202) 383-5300
**Admitted in Illinois only*

Counsel for Amicus Curiae

TABLE OF CONTENTS

Page

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT 1

ARGUMENT 5

I. An Administrative Interpretation Of Federal Commerce Clause Authority Over Local Conduct Is Not Entitled To Deference Under This Court's Federalism Precedents..... 6

A. Localism Is An Important Component Of The American System Of Dual Sovereignty. 6

B. Agency Interpretations Of The Scope Of Federal Commerce Power Deserve No Deference. 9

1. Agencies have an inferior democratic pedigree. 9

2. Where agency decisionmaking risks conflict with a state's democratically-expressed preferences about regulation within the scope of its historic police powers, agency decisionmaking must at a minimum accord with this Court's preference for decisional minimalism..... 12

3. Agency interpretations of the scope of their own regulatory jurisdiction are especially suspect where an agency interprets an ambiguous statute to support a novel expansion of federal rulemaking jurisdiction with enormous social consequences. 17

TABLE OF CONTENTS
(continued)

Page

II. The Ashcroft Directive Fails Scrutiny Under the Necessary and Proper Clause. 21

CONCLUSION 30

TABLE OF AUTHORITIES

Page(s)

CASES

Barsky v. Bd. of Regents,
347 U.S. 442 (1954) 26

Blakely v. Washington,
542 U.S. 296 (2004) 8

Boy Scouts of Am. v. Dale,
530 U.S. 640 (2000) 9

Chevron U.S.A., Inc. v. Natural Res. Def. Council,
467 U.S. 837 (1984) 9

Colorado Republican Fed. Campaign Comm. v. Fed. Election Comm'n,
518 U.S. 604 (1996) 13

Cruzan v. Director, Missouri Dep't of Health,
497 U.S. 261 (1990) 18, 19

Equality Found. v. City of Cincinnati,
Nos. 94-3855, 94-3973, 94-4280,
1998 U.S. App. LEXIS 1765 (6th Cir. Feb. 5, 1998) 20

FDA v. Brown & Williamson Tobacco Corp.,
529 U.S. 120 (2000) 18

Gonzales v. Raich,
125 S. Ct. 2195 (2005) ..... *passim*

INS v. Chadha,
462 U.S. 919 (1983) 27

Katzenbach v. McClung,
379 U.S. 294 (1964) 21

Kent v. Dulles,
357 U.S. 116 (1958) 18

TABLE OF AUTHORITIES
(continued)

Page(s)

Linder v. United States,
268 U.S. 5 (1925) 24, 26

McCulloch v. Maryland,
17 U.S. (4 Wheat.) 316 (1819) ..... *passim*

New York v. United States,
505 U.S. 144 (1992) 26, 28, 29

Oregon v. Ashcroft,
368 F.3d 1118 (9th Cir. 2004) 11, 25

Printz v. United States,
521 U.S. 898 (1997) 27, 28

Rodgers v. Fed. Trade Comm'n,
492 F.2d 228 (9th Cir. 1974) 26

Sabri v. United States,
541 U.S. 600 (2004) 22, 23

Solid Waste Agency v. United States Army Corps of Eng'rs,
531 U.S. 159 (2001) 3, 10

New State Ice Co. v. Liebmann,
285 U.S. 262 (1932) 4

United States v. Dewitt,
76 U.S. (9 Wall.) 41 (1870) 21

United States v. Lopez,
514 U.S. 549 (1995) 1, 5

United States v. Morrison,
529 U.S. 598 (2000) 2

United States v. Oakland Cannabis Buyers' Coop.,
532 U.S. 483 (2001) 8, 20

United States v. Salerno,
481 U.S. 739 (1987) 13

TABLE OF AUTHORITIES
(continued)

Page(s)

United States v. Virginia,
518 U.S. 515 (1996) 9, 13

Vacco v. Quill,
521 U.S. 793 (1997) 20, 29

Washington v. Glucksberg,
521 U.S. 702 (1997) 2, 19, 29

CONSTITUTIONAL PROVISIONS

U.S. Const. amend. I-IX 28

U.S. Const. amend. X 17

U.S. Const. amend. XIV 28

STATUTES AND REGULATIONS

Controlled Substances Act, 21 U.S.C. § 801 *et seq.* 2

21 U.S.C. § 812 ..... *passim*

21 U.S.C. § 822 25

21 U.S.C. § 829 ..... *passim*

42 U.S.C. § 290bb-2a 11

21 C.F.R. § 1306.04 ..... 11, 24

21 C.F.R. § 1308.11 14

Dispensing of Controlled Substances to Assist Suicide,
66 Fed. Reg. 56,607 (Nov. 9, 2001) 24, 27, 28

OTHER AUTHORITIES

Lynn A. Baker & Ernest A. Young, *Federalism and the Double Standard*, 51 Duke L.J. 75 (2001) 8

TABLE OF AUTHORITIES
(continued)

Page(s)

Sam Bagenstos, *Commerce Clause Doctrine and Practicalities*, http://www.scotusblog.com/movabletype/archives/2005/06/commerce_clause.html (June 6, 2005) 11

Dan T. Coenen, *The Rehnquist Court, Structural Due Process, and Semisubstantive Constitutional Review*, 75 S. Cal. L. Rev. 1281 (2002) 18

The Federalist (Clinton Rossiter ed., 1961) 6, 7

James G. Hodge, Jr., *The Role of Federalism and Public Health Law*, 12 J.L. & Health 309 (1997) 7

Lawrence Lessig, *Translating Federalism: United States v. Lopez*, 1995 Sup. Ct. Rev. 125 (1995) 22

Michael W. McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. Chi. L. Rev. 1484 (1987) 7, 8

Andrzej Rapaczynski, *From Sovereignty to Process: The Jurisprudence of Federalism After Garcia*, 1985 Sup. Ct. Rev. 341 8

Cass R. Sunstein, *Foreword: Leaving Things Undecided*, 110 Harv. L. Rev. 6 (1996) 4, 13

Charles M. Tiebout, *A Pure Theory of Local Expenditures*, 64 J. Pol. Econ. 416 (1956) 7

Alexis de Tocqueville, *Democracy in America* 181 (Henry Reeve trans., 1961) 6

Edward L. Rubin & Malcolm Feeley, *Federalism: Some Notes on a National Neurosis*, 41 UCLA L. Rev. 903 (1994) 8

Ernest A. Young, *Deference to Whom?*, http://www.scotusblog.com/movabletype/archives/2005/06/deference_to_wh.html (June 6, 2005) 11-12

BRIEF OF THE CATO INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF AMICUS CURIAE[1]

The Cato Institute was established in 1977 as a non-partisan public policy research foundation decided to advancing the principles of individual liberty, free markets, and limited government. Cato's Center for Constitutional Studies was established in 1989 to help restore the principles of limited constitutional government, especially the idea that the U.S. Constitution establishes a government of delegated, enumerated, and thus limited powers. Toward that end, the Institute and the Center undertake a wide range of publications and programs, including, notably, publication of the *Cato Supreme Court Review*. The instant case raises squarely the question of the limits of the federal government's power under the doctrine of enumerated powers and is thus of central interest to the Cato Institute and its Center for Constitutional Studies

SUMMARY OF ARGUMENT

This case requires the Court to determine the limits of federal power and the extent of state sovereignty in the area of professional medical judgment – an area of professional regulation to which "States lay claim by right of history and expertise." *United States v. Lopez*, 514 U.S. 549, 583 (1995) (Kennedy and O'Connor, JJ., concurring). Here, an unelected regulatory agent of the executive branch of the federal government has attempted to void, through *administrative*

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[1] In conformity with Supreme Court Rule 37, amicus has obtained the consent of the parties to the filing of this brief and letters of consent have been filed with the Clerk. *Amicus* also states that counsel for a party did not author this brief in whole or in part; and no person or entities other than the *amicus*, its members, and counsel made a monetary contribution to the preparation and submission of this brief.

action, not one but two ballot referenda duly conducted by the citizens of a sovereign state who sought to secure for themselves the right to obtain medical advice and assistance at the end of life. The two referenda at issue, enshrined in Oregon's "Death With Dignity Act," are part of an intense, morally charged debate as to which there is no national consensus, as is evidenced by the Court's several opinions in *Washington v. Glucksberg*, 521 U.S. 702 (1997). Oregon's law may be unorthodox, and even unique, but it has twice been endorsed by substantial majorities of Oregon voters.

Because the administrative decision at issue (known as the "Ashcroft Directive") purports to interpret a federal statute (the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA")) and related regulations that are premised on Congress' power under the Commerce Clause, the Court is called upon in this case to articulate the principle that distinguishes local from truly national concerns that are legitimately subject to regulation by the federal government. The Court's recent decisions define the precedential terminal points of the spectrum, with *Lopez* and *United States v. Morrison*, 529 U.S. 598 (2000), providing examples of local issues not properly subject to federal regulation, and *Gonzales v. Raich*, 125 S. Ct. 2195 (2005), providing an example of an issue the Court considers to be properly within the federal commerce power.

But as the multiplicity of opinions in *Raich* makes clear, defining where Congress' Commerce power ends and a state's role as primary expositor of social policy begins is a controversial inquiry, the relevant considerations for which this Court should identify with greater clarity. This concern is especially pressing here, since the expansive understanding of the commerce power on which the Ashcroft Directive is implicitly premised places in historic peril the very "notion of enumerated powers – a structural principle that is as much a part of the Constitution as the Tenth Amendment's explicit textual command" that powers not delegated to the federal

government are reserved to the states. *Raich*, 125 S. Ct. at 2226 (O'Connor and Thomas, JJ., and Rehnquist, C.J., dissenting).

That peril, while real, is nonetheless easy to avoid in this case. While *amicus* does not believe that the Court's current analysis of the commerce power accords with the Constitution's text, structure, or original meaning, to the extent that this Court is committed to following existing precedents, those precedents do make ***this*** case an easy call.

First, the Court's cases reflect a constitutional preference for democratically pedigreed judgments about the scope of what is national and what is local. Arguably, the Court's preference for democratically pedigreed balancing of national and local interests won the day in *Raich*, which suggested that Congress is the preferred expositor of what is local and national when Congress decides to "comprehensively" regulate an item that travels in interstate commerce. Even assuming, *arguendo*, that such deference was constitutionally proper, there is no basis for extending similar deference to an administrative agency's interpretation of the scope of federal commerce power. Agencies lack the democratic pedigree of Congress, to say nothing of the state referenda at issue. When an agency acts to supplant or undermine the outcome of direct democracy at the state level, as here, its judgment must be categorically disfavored. *Cf. Solid Waste Agency v. United States Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001) (refusing to accord deference to administrative decision that is contrary to unambiguous legislative text and imposing a heightened standard of review where a federal administrative interpretation would interfere with democratic decisions at the state level).

Second, the Court's recent constitutional jurisprudence reflects a possible preference for narrow over broad judicial decisions, perhaps because it is thought that narrow judicial decisions "can be democracy-forcing, not only in the sense

that [they] leave[] issues open for democratic deliberation, but also and more fundamentally in the sense that [they] promote[] reason-giving and ensure[] that certain important decisions are made by democratically accountable actors." Cass R. Sunstein, *Foreword: Leaving Things Undecided*, 110 Harv. L. Rev. 6, 7 (1996). Whatever the general merits of this principle, *amicus* believes it is fully defensible as a governing principle for decisionmaking by federal *administrators*, especially when an administrative judgment purports to trump, in whole or in part, the judgments of local decisionmakers with both a superior democratic pedigree and a historic claim to regulatory primacy.

And, finally, since the days of Justice Brandeis, at least, numerous members of the Court have recognized a constitutional preference for state over federal regulation, based on the propensity for "a single courageous State [to] serve as a laboratory . . . and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). This latter concern is especially relevant where, as here, (1) a state provides an escape hatch for dissenters seeking relief from competing legal regimes, and (2) does so in a fashion that the federal regulators themselves recognize imposes *no costs* on the interstate system. Indeed, it is in precisely this circumstance that Brandeis's laboratory justification for federalism is most potent: the state's heterodox policy decisions provide, at little cost to anyone, a wealth of information about untried competing policies that have been suppressed and silenced elsewhere.

All of these considerations are fully consistent with the outcomes of *Lopez*, *Morrison*, and *Raich*, and conclusively counsel against the Ashcroft Directive. The decision of the court below invalidating the Attorney General's interpretation should be affirmed.

ARGUMENT

The Court's federalism decisions over the past decade – particularly *Lopez*, *Morrison*, and *Raich* – reflect the Court's difficulty crafting a bright-line rule that determines when a federal government of limited and enumerated powers may decide controversial questions of social policy under Congress' power to regulate interstate commerce. But the difficulty of identifying a bright-line rule by no means reduces the importance of articulating relevant constitutional considerations that take seriously the concepts, integral to our constitutional order, of dual sovereignty and limited government. The "federal balance is too essential a part of our constitutional structure and plays too vital a role in securing freedom" for this Court "to admit inability to intervene when one or the other level of Government has tipped the scales too far." *Lopez*, 514 U.S. at 578 (Kennedy and O'Connor, JJ., concurring).

This Court's precedents underscore, at a minimum, that whatever deference is due to "comprehensive" *legislative* judgments about the scope of the commerce power under *Raich* –*administrative* judgments do not deserve similar deference. Viewed in light even of *Raich*'s counsel of deference to democratic fact-finding about the scope of the commerce power, the Ashcroft Directive exceeds any plausible construction of permissible federal legislative authority.

The Ashcroft Directive also fails Commerce Clause scrutiny for a separate reason: It is neither "necessary" nor "proper" to the exercise of any enumerated Article I federal power, as those standards were articulated in *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819). As such, the Court should hold the Directive without effect – and do so without reference to any degree of "deference" putatively owed either Congress or agency regulators under *Raich*.

I. AN ADMINISTRATIVE INTERPRETATION OF FEDERAL COMMERCE CLAUSE AUTHORITY OVER LOCAL CONDUCT IS NOT ENTITLED TO DEFERENCE UNDER THIS COURT'S FEDERALISM PRECEDENTS.

A. Localism Is An Important Component Of The American System Of Dual Sovereignty.

Tocqueville recognized during his travels in early America that "the love and the habits of republican government in the United States were engendered in the township and in the provincial assemblies . . . [I]t is this same republican spirit, it is these manners and customs of a free people, which are engendered and nurtured in the different States, to be afterwards applied to the country at large." Alexis de Tocqueville, *Democracy in America* 181 (Henry Reeve trans., 1961).

Protecting local republican government from encroachment by the central government is, of course, a defining feature of the unique American constitutional framework. As the authors of *The Federalist* explained, the "powers delegated . . . to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite [and] extend to all the objects, which . . . concern the lives, liberties, and properties of the people. . . . " *The Federalist* No. 45, at 292-93 (James Madison) (Clinton Rossiter ed., 1961). Indeed, one of the principal criticisms of the new Constitution was that "it would tend to render the government of the Union too powerful, and to enable it to absorb those residuary authorities, which it might be judged proper to leave with the States for local purposes." *The Federalist* No. 17, at 118 (Alexander Hamilton).

To this concern, the proponents of the Constitution offered two basic rebuttals. First, because of state governments' closer geographic proximity to their citizens, "the people of

each State would be apt to feel a stronger bias towards their local governments than toward the government of the Union," with the result that the people generally will look to state government as "the immediate and visible guardian of life and property." *Id.* at 119-20. Second, because of the regulatory competition inherent in a system of dual sovereignty, "a double security arises to the rights of the people. The different governments will control each other, at the same time that each will be controlled by itself." *The Federalist* No. 51, at 323 (James Madison).

The second point is especially salient here: competition between different local jurisdictions plays an important role in protecting the welfare of ordinary Americans, just as competition in the economy furthers overall general welfare. "[S]maller units of government have an incentive, beyond the mere political process, to adopt popular policies . . . Since most people are taxpayers this means that there is a powerful incentive for decentralized governments to make things better for most people." Michael W. McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. Chi. L. Rev. 1484, 1498-99 (1987); *cf.* Charles M. Tiebout, *A Pure Theory of Local Expenditures*, 64 J. Pol. Econ. 416 (1956). In short, a system that favors state over federal regulation brings to social policy the same benefits that competition brings to economic policy – by increasing options that better balance competing interests. *See* James G. Hodge, Jr., *The Role of Federalism and Public Health Law*, 12 J.L. & Health 309, 356 (1997) ("The reality of the federal political process is that federal legislation and regulation invariably represents a mediocre compromise to the accomplishment of specific goals . . . [w]hile . . . state governments are generally more responsive to the needs of their citizenry").

Pluralism among local sovereignties is also information-forcing. The very purpose of the states' role as laboratories of social experimentation is to foster unorthodox ideas – even ideas that may be anathema in other parts of the country – and

thereby inform the judgments of competing sovereignties, state and local. Unorthodoxy may bring information to light that reigning common wisdom has ignored. And it may expose error – and hence promote consensus – far more effectively than the imposition of an artificial consensus by national fiat.[2]

The significance of states' role as laboratories of social experimentation – and its obvious import here, where Oregon has launched a nationally unorthodox but locally popular experiment in end-of-life decisionmaking – is underscored by the number of times members of this Court have invoked the concept to defend the right of the states to experiment free from federal interference. *See, e.g., Raich*, 125 S. Ct. at 2234-35 (O'Connor, J., Rehnquist, C.J., and Thomas, J., dissenting); *Blakely v. Washington*, 542 U.S. 296 (2004) (Kennedy and Breyer, JJ., dissenting); *United States v. Oakland Cannabis*

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[2] Indeed, the information-forcing component of federalism and its role in promoting liberty go hand in hand, since the raw data that local pluralism produces is the product of free individual choices between competing legal regimes that might otherwise be suppressed. Put another way, "[f]ederalism provides an additional level of freedom to individuals, beyond that provided by specific guarantees of individual rights, by conferring the freedom to choose from among various diverse regulatory regimes the one that best suits the individual's preferences." Lynn A. Baker & Ernest A. Young, *Federalism and the Double Standard*, 51 Duke L.J. 75, 138-39 (2001); *see also* McConnell, *supra,* at 1506 ("Given the diversity of views about issues of morality, and the potential for [political] oppression, it is natural that lovers of liberty would be inclined toward decentralized decision making."); Edward L. Rubin & Malcolm Feeley, *Federalism: Some Notes on a National Neurosis*, 41 UCLA L. Rev. 903, 912 (1994) (noting that the "point of federalism . . . is to allow normative disagreement amongst the subordinate units so that different units can subscribe to different value systems"); *see also* Andrzej Rapaczynski, *From Sovereignty to Process: The Jurisprudence of Federalism After Garcia*, 1985 Sup. Ct. Rev. 341, 400 ("The model of participatory government [views] political activity not as instrumental toward achieving a proportionate share in distribution of available resources, [but] rather as a good in itself, something essentially implicated in the very concept of human freedom.").

Buyers' Coop., 532 U.S. 483, 502 (2001) (Stevens, Souter, and Ginsburg, JJ., concurring in the judgment); *Boy Scouts of Am. v. Dale*, 530 U.S. 640, 664 (2000) (Stevens, Souter, Ginsburg, Breyer, JJ., dissenting); *United States v. Virginia*, 518 U.S. 515, 600 (1996) (Scalia, J., dissenting).

B. Agency Interpretations Of The Scope Of Federal Commerce Power Deserve No Deference.

Despite the importance of localism in our constitutional federal framework, *Raich* suggested that Congress deserves deference when interpreting the scope of its commerce power over local conduct within the province of a comprehensive federal regulatory scheme. The Court in *Raich* reasoned that (1) a representative body composed of different sectional interests is best suited to identify what is national and what is local within the framework of a comprehensive regulatory scheme and that (2) this deference is most appropriate where the legislative judgment identifying what is national and what is local is evident on the face of a legislative enactment. Whatever the merits of that argument, the rationale of *Raich* does not apply in this case, when the federal judgment about the scope of federal commerce power is made by an *administrative agency* and is made in the course of interpreting an ambiguous statutory enactment.

1. Agencies have an inferior democratic pedigree.

First, in various contexts, the Court's decisions evidence marked suspicion of administrative judgments that conflict with accountable legislative judgments of Congress. The Court's most important decision involving deference to legal interpretations of administrative agencies, for example, makes clear that where a federal agency interprets a statute in a manner contrary to the unambiguous text of the statute, the statutory text – because of its democratic provenance – prevails. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984). More recently, the

Court held the administrative interpretations even of ambiguous federal statutory text are subject to special scrutiny when they impinge on state laws. In *Solid Waste Agency v. United States Army Corps of Engineers*, the Court invalidated a federal environmental regulation on the ground that it was not supported by a "clear indication that Congress intended that" regulation, noting that the need for a clear statement from Congress "is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power." 531 U.S. at 173.

The logic of these and similar authorities is fully applicable to Commerce Clause analysis under *Raich* in this case. First, in *Raich,* the intent of Congress to impose a "comprehensive" ban on marijuana distribution was evident from the face of the comprehensive legislative enactment, a fact the Court held counseled deference. *Raich*, 125 S. Ct. at 2204 (discussing treatment of marijuana under the CSA); *id.* at 2208 n.32 (noting that Congress's detailed "findings regarding the effects of intrastate drug activity on interstate commerce" rendered claims that Congress had not specified its intent to reach the conduct at issue with sufficient clarity "unfounded"). Yet, here, as explained in detail by the court of appeals, the parties, and other *amici*, the Attorney General's (putative) authority to regulate end-of-life medical decisionmaking is hardly self-evident from the text and structure of the CSA. The CSA was designed to address drug "abuse" – a word the Act's text, implementing regulations, and legislative history pervasively conflate with the health effects of "addiction" or "dependence," an issue not implicated here. *Cf. Raich*, 125 S. Ct. at 2203-04 (observing that "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances," and that the term "abuse," as used in the CSA schedules, is related to risks of "severe psychological or physical dependence"). Nor does the Act or its implementing regulations explicitly define the

textual term invoked by the Directive – "legitimate medical purpose" (21 C.F.R. § 1306.04) – to justify excluding drugs used for assisted suicide from the universe of statutorily permissible medical uses. Finally, the Act is designed to empower the "principal health agency of the federal government," not the Attorney General, to make medical decisions under the Act – an enforcement choice that is animated, as the court of appeals rightly noted, by a concern about the impropriety "of having federal officials determine the appropriate method of the practice of medicine." *Oregon v. Ashcroft*, 368 F.3d 1118, 1128 (9th Cir. 2004) (quoting H.R. Rep. No. 91-1444 (1970)); *cf. also* 42 U.S.C. § 290bb-2a (*quoted in United States v. Moore*, 423 U.S. 122, 144 (1975)).

Indeed, for these reasons Attorney General Ashcroft's predecessor, Janet Reno, refused to use her CSA enforcement powers as a basis for regulating end-of-life medical decisionmaking. *Cf. Ashcroft*, 368 F.3d at 1123. Then-Attorney General Reno observed in 1998 that the CSA was not "intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice." *Id.* (citations omitted). With respect to Oregon's Death With Dignity Act, she opined that "the CSA does not authorize [the federal government] to prosecute, or to revoke DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." *Id.*

Second, *Raich* presumes that the job of balancing what is national and what is local under a comprehensive legislative scheme is best left to the body with the superior democratic pedigree. *See, e.g.*, Sam Bagenstos, *Commerce Clause Doctrine and Practicalities*, http://www.scotusblog.com/movabletype/archives/2005/06/commerce_clause.html (June 6, 2005) (noting *Raich* may reflect a preference for assessment of the "practical facts on the ground" by Congress instead of courts); Ernest A. Young, *Deference to Whom?*,

http://www.scotusblog.com/movabletype/archives/2005/06/deference_to_wh.html (June 6, 2005) (noting that *Raich* reflects "arguments about comparative institutional competence between courts and legislatures"). Here, the Attorney General's interpretation is in conflict with a clear and far more democratically pedigreed judgment – that of the people of Oregon. To be sure, state democratic processes are not always entitled to deference – as where, for example, their judgment conflicts with the Constitution or validly enacted legislative enactments within the scope of Congress' Article I powers. But, in cases where, as here, states act within the province of their traditional police power, and in conflict with a federal administrative decree issued under an ambiguous federal enactment, the sovereign democratic judgment of the state deserves *at least* the same priority as the clear statement of federal legislative will considered determinative in *Raich*.

Given the lack of any indication that Congress intended to make the Attorney General America's foremost regulator of medical decisionmaking for the terminally ill, the Court should take care to underscore that the Attorney General is not entitled to any deference under the Commerce Clause when he acts to expand federal legislative jurisdiction in a fashion that supplants, or undermines, Oregon's clear sovereign judgments.

2. Where agency decisionmaking risks conflict with a state's democratically-expressed preferences about regulation within the scope of its historic police powers, agency decisionmaking must at a minimum accord with this Court's preference for decisional minimalism.

The Court's recent decisions have evidenced a preference for "judicial minimalism": *i.e.*, a concern for protecting the widest possible field for democratic decisionmaking against incursions from the judicial apparatus of the government. *Amicus* is skeptical of strong claims for judicial minimalism,

including its predicate assumption that majoritarian decisionmaking is generally rational and benign. Nonetheless, as suggested by some of this Court's recent precedents, the preference for decisional minimalism weighs especially heavily against deference to *agency* determinations about the scope of federal commerce power in this case.

Some commentators defend judicial minimalism as an approach that promotes greater public participation in democratic decisionmaking: "One of the major advantages of minimalism is that it grants a certain latitude to other branches of government by allowing the democratic process room to adapt to future developments, to produce mutually advantageous compromises, and to add new information and perspectives to legal problems[.]" Sunstein, *supra*, at 19. This "minimalist" approach arguably is reflected in such decisions as *United States v. Salerno*, 481 U.S. 739, 745 (1987), where the Court expressed greater reluctance to accept a facial challenge to a statute than a narrower as-applied challenge; *United States v. Virginia*, 518 U.S. 515, 533 n.7 (1996) (citation omitted), where the Court decided an issue of major national controversy – the admission of women to a historically single-sex military college – while emphasizing that it "address[ed] specifically and only an educational opportunity recognized by the District Court and the Court of Appeals as 'unique' . . . ."; and *Colorado Republican Federal Campaign Comm. v. Fed. Election Comm'n*, 518 U.S. 604, 623-24 (1996), where the Court noted a "prudential reason for this Court not to decide the broader question" presented by a facial challenge to an election law.

To the extent the Court considers decisional minimalism a compelling basis of decision for courts, minimalism should certainly be the constitutionally preferred mode of decision when administrative *agencies* either explicitly or, in this case, implicitly interpret the scope of their own regulatory power under the Commerce Clause. After all, agencies, like courts, act without a strong democratic pedigree; worse, they lack the

constitutional authority that courts possess to engage in judicial review of state judicial systems. Thus, agencies' authority is especially insubstantial when they interpret the scope of their own delegated commerce power in derogation of express policies enacted through state democratic processes. On this score, the Ashcroft Directive is particularly objectionable, since it (1) cuts the widest conceivable berth for agency action in a situation where the statute it purports to enforce (the CSA) supplies scant textual justification for such action and (2) purports to thwart multiple state democratic referenda within the field of traditional state competence.

Furthermore, and more fundamentally still, principles of decisional minimalism also should apply with equal force to this Court's decision in *Gonzales v. Raich*. If courts should decide cases narrowly, then *Raich* itself must be read narrowly rather than broadly, in order to preserve the widest possible field for sovereign decisionmaking within the scope of states' police powers. That, at a minimum, means that *Raich* should be construed against extension to cases raising dissimilar facts.

Raich, of course, involved a very different set of facts from this case. For example:

- In *Raich*, the Court was asked to distinguish what is national from what is local in light of congressional imposition of a comprehensive nationwide ban on a particular controlled substance, marijuana. *See, e.g.*, 21 C.F.R. § 1308.11(c)(11), (d)(18)-(21) (classifying substances including marijuana, heroin, and lysergic acid as Schedule I substances); 21 U.S.C. § 812(b)(1) (Schedule I substances have a high potential for "abuse," no "currently accepted medical use," and "lack of accepted safety for use"); *id.* at § 829 (authorizing prescription only for Schedule II, III, IV, and V drugs); *Raich*, 125 S. Ct. at 2211 ("The CSA designates marijuana as contraband for *any* purpose") (emphasis in original). Here, by contrast, there is no

such ban: the substances in question are classified under Schedule II and III of the Controlled Substances Act, 21 U.S.C. § 812(b)(2), (b)(3). Under Schedule II and III, a legal market for these substances is permitted as a matter of federal law, contingent on the medical context in which those substances are used. *See, e.g.*, 21 U.S.C. § 812(b)(2), (b)(3) (defining Schedule II and III substances as those that have a "currently accepted medical use in treatment"); *id.* § 829(a) (authorizing dispensation of Schedule II drugs with "the written prescription of a practitioner"); *id.* § 829(b) (authorizing dispensation of Schedule III drugs with "a written or oral prescription").

- In *Raich*, the Court confronted what it deemed a compelling practical problem: namely, that replacing a bright-line ban on marijuana with a conditional ban in which use of the drug is legal or illegal depending on the medical context of use (the necessary result of deferring to California law at the federal level, as respondents in *Raich* effectively urged) would complicate enforcement of Schedule I. *See, e.g.*, *Raich*, 125 S. Ct. at 2213 (the "notion that California law has surgically excised a discrete activity that is hermetically sealed off from the larger interstate marijuana market is a dubious proposition"); *id.* at 2220 (Scalia, J., concurring) (suggesting federal enforcement of a ban on interstate trafficking of marijuana would be rendered "precarious" by California's Compassionate Use Act, since "medical" marijuana is "never more than an instant from the interstate market"). Here, that enforcement concern is non-existent—since no bright-line ban is in place. Instead, under the CSA, *all* enforcement decisions with respect to Schedule II and III drugs turn on contextual medical circumstances of use. *See, e.g.*, 21 U.S.C. § 812(b)(2), (3) (defining Schedule II and III drugs as

drugs with "currently accepted" medical uses); *id.* at § 829(b) (authorizing dispensation of Schedule II drugs when prescribed by a physician). As a result, the enforcement concerns raised in *Raich* are plainly not applicable here. Oregon's law does not alter the fact that distinguishing illegal and legal uses as a matter of federal law remains fact-specific.

- In *Raich*, Congress was concerned that isolated lawful use of the comprehensively banned substance, marijuana, might affect the price of the substance that moves in the illicit interstate market. *Raich*, 125 S. Ct. at 2207 ("Congress had a rational basis for believing that, when viewed in the aggregate, leaving [marijuana] outside the regulatory scheme would have a substantial influence on price and market conditions"). That concern, again, reflected the nature of the federal controls at issue in that case – which imposed a comprehensive ban designed to make purchase of the substance, marijuana, prohibitively expensive. Here, however, there is no evidence that Congress is concerned with making Schedule II or III substances prohibitively expensive. To the contrary, the plain text of Schedule II and III underscores that Congress is concerned primarily that these substances are used in accordance with medical judgment. *See, e.g.*, 21 U.S.C. § 812(b)(1)-(3) (distinguishing Schedule II and III drugs from Schedule I drugs based on the existence of "currently accepted" medical uses for these drugs); *id.* § 829(a) (treating Schedule II and III drugs differently from Schedule I drugs by authorizing dispensation of the former when made pursuant to prescription).

- Finally, as discussed above, in *Raich* the Court considered what it deemed to be a clear statement by Congress in favor of a total ban on Schedule I

controlled substances. Here, by contrast, the Court is asked to consider an Article II officer's interpretation of his delegated authority under a patently unclear legislative enactment.

In short, the regulatory setting considered here is very different from that at issue in *Raich*. This case asks the Court to permit a federal administrative officer to void multiple statewide democratic referenda concerning an activity that implicates no clearly expressed legislative policy and that poses no risk of diversion, enforcement confusion, or price effects for a comprehensively banned substance. At bottom, the executive branch asks to impose its policy judgments about end-of-life decisions on Oregon, supplanting the clearly expressed judgments of that state's citizens. And it does so based on uncertain Article I legislative authorization. If there is ever a case where "judicial minimalism" in the interpretation of precedent is called for, it is here: On the facts of this case, the Court should explicitly hold that *Raich* is inapplicable and further hold that, at a minimum, additional legislative guidance is necessary before the federal commerce power possibly can be construed, whether explicitly or, as here, *sub silentio*, to authorize imposition of the federal policy favored by a single executive officer, the Attorney General, on Oregon's electorate.

3. Agency interpretations of the scope of their own regulatory jurisdiction are especially suspect where an agency interprets an ambiguous statute to support a novel expansion of federal rulemaking jurisdiction with enormous social consequences.

Finally, any deference due to administrative agencies' interpretations of the scope of their own Commerce Clause power is especially weak where, as here, the choice is morally contentious and committed, by tradition and constitutional text (U.S. Const. amend. X), to state police power. "[O]ne might claim that courts, when interpreting statutes, should assume in

close cases that a decision with 'enormous social consequences' . . . should be made by democratically elected Members of Congress rather than by unelected agency administrators." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 190 (2000) (Breyer, Stevens, Souter and Ginsburg, JJ., dissenting) (citations omitted). And, indeed, cases like *Kent v. Dulles*, 357 U.S. 116, 129 (1958), picture the Court's use of that very canon to "ensure that certain decisions are made by Congress rather than the executive branch" when "they involve constitutionally sensitive domains" and threaten "to make rules interfering with [the] exercise of basic human liberties." Dan T. Coenen, *The Rehnquist Court, Structural Due Process, and Semisubstantive Constitutional Review*, 75 S. Cal. L. Rev. 1281, 1374 (2002) (quoting *Brown & Williamson*, 529 U.S. at 190 (Breyer, Stevens, Souter and Ginsburg, JJ., dissenting)); *cf. also Kent*, 357 U.S. at 130 (narrowly construing grant of congressional authority invoked by the Secretary of State in promulgating a rule that prohibited the award of passports to Communist Party members because "[w]e would be faced with important constitutional questions were we to hold that Congress . . . had given the Secretary authority to withhold passports to citizens because of their beliefs or associations").

Such concerns are also apt here. This Court's cases concerning the role of physicians in advising terminally ill patients on end-of-life decisions make clear that, precisely because of the controversial and unsettled nature of the issue, politically accountable actors like individual ***state*** governments should be permitted to experiment through the democratic process. In *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990), the Court granted certiorari to decide whether the Constitution permits a state to impose a heightened evidentiary standard for justifying withdrawal of artificial hydration and nutrition from a comatose patient. Various members of the Court described that question as presenting "difficult and sensitive" and even "agonizing"

issues, *id.* at 292 (O'Connor, J., concurring), 292 (Scalia, J., concurring), but ultimately concluded that the Constitution permitted a state to take that position – with the caveat that that holding would not "prevent States from developing other approaches for protecting an incompetent individual's liberty interest in refusing medical treatment." *Id.* at 292 (O'Connor, J., concurring).

In *Glucksberg*, the Court granted certiorari to decide whether a state has the power to prohibit actions that cause or assist suicide. While noting that the states – and particularly Oregon – were "currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues," the Court nonetheless concluded that it was a legitimate expression of the state political will to prohibit assisted suicide. *Glucksberg*, 521 U.S. at 719. Members of this Court took pains to point out, however, that a prohibition on end-of-life medical advice, including assisted suicide, is not the only permissible judgment a state might reach. As Justice O'Connor observed, "[t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly under pressure." *Id.* at 737 (O'Connor, Ginsburg, and Breyer, JJ., concurring) (citing, *inter alia*, *New State Ice*). And Justice Stevens emphasized the importance of permitting the "continuation of the vigorous debate about the 'morality, legality, and practicality of physician-assisted suicide' in a democratic society," *id.* at 738 (Stevens, J., concurring), particularly in view of the fact that there is a "specific [constitutional] interest in making decisions about how to confront an imminent death." *Id.* at 745.

In *Vacco v. Quill*, as in *Glucksberg*, the Court granted certiorari to decide whether a state has the power to prohibit or limit assisted suicide. Again, members of this Court endorsed the view that the propriety of physicians' involvement in end-

of-life decisions, including assisted suicide, was a matter best left to democratic debate at the state level. *See* 521 U.S. 793, 809 (1997) (O'Connor, Ginsburg, and Breyer, JJ., concurring) (citing *New State Ice*). And again, Justice Stevens emphasized that there is "room for further debate" about the constitutional limits on suicide-assistance prohibitions. *Id.* (Stevens, J., concurring).[3]

Cruzan, *Glucksberg*, and *Vacco*, then, each raised a highly controversial question: whether the Constitution permits states to place limits on the right of individuals to determine the time and manner of their own deaths, and their associated right to seek assistance in doing so. This question was considered sufficiently debatable to warrant review by writ of certiorari. Each time, members of this Court concluded that the state laws in question were permissible in part because of the states' role in the constitutional order as laboratories of social experimentation. Yet it surely cannot be that if a state's power to prohibit end-of-life medical assistance is a close constitutional question, justifiable largely on the ground that states have the freedom to experiment with social policy, other states such as Oregon may be legally *required* to make that same political choice by an unelected federal administrator. *Cf. Equality Found. v. City of Cincinnati*, Nos. 94-3855, 94-3973, 94-4280, 1998 U.S. App. LEXIS 1765, at *4-5 (6th Cir. Feb. 5, 1998) (Boggs, J., concurring in denial of reh'g en banc) (noting that "[i]f in *Romer* [*v. Evans*] the Supreme Court held that cities may choose to enact gay-right ordinances without nullification by state constitutional amendment, it did not hold that cities must choose to do so"); *cf. also Brown & Williamson*, 529 U.S. at 190 (Breyer, Stevens, Souter and

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[3] It is significant in the context of this case that three members of the Court have separately emphasized the "importance of showing respect for the sovereign States that comprise our Federal Union" when it comes to reviewing state laws authorizing certain seriously ill individuals to use otherwise illegal drugs. *Oakland Cannabis*, 532 U.S. at 502 (citing *New State Ice*) (Stevens, Souter, and Ginsburg, JJ., concurring in the judgment).

Ginsburg, JJ., dissenting).

II. THE ASHCROFT DIRECTIVE FAILS SCRUTINY UNDER THE NECESSARY AND PROPER CLAUSE.

As Justice Scalia noted in his *Raich* concurrence, "activities that substantially affect interstate commerce are not themselves part of interstate commerce, and thus the power to regulate them cannot come from the Commerce Clause alone." 125 S. Ct at 2215-16 (Scalia, J., concurring). Federal regulatory power over such activities comes from the Necessary and Proper Clause and the Commerce Clause taken together. *Id.; cf. also Katzenbach v. McClung*, 379 U.S. 294, 301-02 (1964). Justice Marshall in *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819), articulated the test for determining when congressional action in effectuation of an enumerated power is permissible under the Necessary and Proper Clause: "Let the end be legitimate, let it be within the scope of the constitution, and all means which are appropriate, which are plainly adapted to that end, which are not prohibited, but consist with the letter and spirit of the constitution, are constitutional." *Id.*

The Ashcroft Directive fails these tests. It is neither a "necessary" nor a "proper" means for making effective the CSA's regulation of interstate commerce in controlled substances.

1. To act in effectuation of an enumerated power under the "necessity" prong of the Necessary and Proper Clause, Congress must select a means that is "appropriate" and "plainly adapted" to executing an enumerated power. *Raich*, 125 S. Ct. at 2219 (Scalia, J., concurring) (citation omitted). *Cf. also id.* at 2231 (Thomas, J., dissenting); *United States v. Dewitt*, 76 U.S. (9 Wall.) 41, 44 (1870) (finding ban on intrastate sale of lighting oils not "appropriate and plainly adapted means for carrying into execution" Congress' taxing power). A means is "plainly adapted" if there is an "obvious,"

"simple," and "precise" connection between the means and the constitutional ends. *Sabri v. United States*, 541 U.S. 600, 613 (2004) (Thomas, J., concurring) (citation omitted). These requirements "are not merely hortatory." *Raich*, 125 S. Ct. at 2219 (Scalia, J., concurring). Rather, they prevent claims of "necessity" from being used as a "pretext . . . for the accomplishment of objects not entrusted to the government." *McCulloch*, 17 U.S. (4 Wheat.) at 323; *cf. also* Lawrence Lessig, *Translating Federalism: United States v. Lopez*, 1995 Sup. Ct. Rev. 125, 202 (1995) (discussing *McCulloch* and stating that "when Congress regulates according to the Necessary and Proper Clause, either because of the textual requirement of 'propriety' or because of the need to assure that this clause not become the demise of Congress's limited power, the Court should assure that the invocation of this clause not be for improper ends").

The Ashcroft Directive fails this "necessity" test. *Amicus* assumes *arguendo* that the goal by which the "necessity" of the Directive must be measured is defined by Schedule II and III, which articulate the permissible uses of the regulated substances at issue in this case and therefore the scope of federal regulatory purpose at issue. *See, e.g., Raich*, 125 S. Ct. at 2219 (Scalia, J., concurring) (assuming that the relevant level of analysis under the Necessary and Proper Clause is the purpose of the governing statutory scheme, in that case, Schedule I, which aimed to "extinguish the interstate market" in marijuana). Yet, as discussed in Part I, those classifications do not purport to effectuate a comprehensive ban on subject substances. Rather, the classifications are designed to further a different goal: to ensure that the controlled substances, for which an interstate market exists, are prescribed pursuant to medical judgment. *See, e.g.*, 21 U.S.C. § 812(b)(1)-(3) (distinguishing Schedule II and III drugs from Schedule I drugs based on the fact that there are "currently accepted" medical uses for the former); *id.* § 829(a) (authorizing dispensation of Schedule II and III drugs according to a

prescription). While the Ashcroft Directive presumes that a federal role in defining medically legitimate uses is "necessary" to effectuate this goal, there is no "obvious," "simple" rationale for federal involvement in this way. *Sabri*, 541 U.S. at 613 (Thomas, J., concurring).

At the outset, the federal government provides no evidence that Oregon's policy is incompatible with a chosen *form* of federal regulation. In *Raich*, as discussed in Part I, Congress chose to regulate a substance that traveled in interstate commerce by comprehensively *banning* all uses of that substance. The Court recognized that such a ban entailed outlawing local uses of marijuana in all circumstances. Otherwise, the integrity of a total bright-line ban on that substance would have been in jeopardy. For example, placing local uses of a comprehensively banned substance outside Congress' reach would, the Court assumed, create enforcement problems that a bright line ban is designed to obviate and, relatedly, would subvert the effort to drive the substance from the market, a policy effectuated by making the banned substance prohibitively expensive. *See generally* Part I.B.2, *supra*.

Here, however, the chosen form of federal regulation is very different: no total, bright-line ban on relevant controlled substances is in place; instead, the scheme itself anticipates that the Schedule II and III substances at issue here are legal in some contexts and illegal in others, depending on medical judgments about their use in given contexts. *See, e.g.*, 21 U.S.C. § 812(b)(2), (3); *id.* § 829(a). Thus, maintaining the integrity of the chosen form of regulation does not "obviously" (*Sabri*, 541 U.S. at 613 (Thomas, J., concurring)) require a uniform federal judgment about the permissibility of uses. For example, because variation in legality of the substance, depending on context, is ***inherent*** to the regulatory framework as enacted, it cannot be argued that allowing Oregon to make its own decision about the scope of permissible uses raises special enforcement problems that the

chosen form of regulation is designed to preclude. *See* Part I.B.2, *supra*. Nor can it be argued that federal judgment is necessary to maintain a prohibitively high price for a comprehensively banned substance – since Schedule II and III do not attempt to drive any covered substances from the marketplace. 21 U.S.C. § 829(a).

To be sure, some might argue that there is a need for executive branch intervention where states have abdicated their responsibility to clarify the medically permissible uses of Schedule II and III substances, thereby confusing enforcement of the Act. But that is not the case here. To the contrary, the will of Oregon is expressed with simple clarity – albeit in a fashion objectionable to the current executive branch's policy preferences. Nor is there an "obvious" need for uniform federal administrative standards in this case, given the recognized benefits that state pluralism brings to an area of medical regulation that is deeply (and morally) contentious. To the contrary, if any understanding of states' role is "obvious," given the Court's longstanding articulation of the structural underpinnings of federal power, it is that states are the preferred regulators of local medical standards – and, at a bare minimum, are presumptively favored as such in the absence of a clear legislative statement to the contrary. *Linder v. United States*, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government").

Finally, the Ashcroft Directive itself concedes that the Directive, by design, will have *no* cross-border effects whatsoever. *See* Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607, 56,608 (Nov. 9, 2001) (stating the directive "makes no change in the current standards and practices of the DEA in any State other than Oregon"); *cf. also* 21 U.S.C. § 822(b); 21 C.F.R. § 1306.04. When federal regulators themselves recognize that the effects of federal intervention will be confined entirely to a single state, any suggestion that the Ashcroft Directive is necessary

to effectively regulate the ***inter***state distribution of Schedule II and III drugs is completely unavailing, even under the most generous interpretations of this Court's Commerce Clause precedents.[4]

In the end, the Ashcroft Directive is a paradigmatic example of the kind of federal initiative that the test for "necessity" announced by Chief Justice Marshall in *McCulloch v. Maryland* is designed to combat. *McCulloch*, 17 U.S. (4 Wheat.) at 323 (Necessary and Proper Clause may not be used as a "pretext . . . for the accomplishment of objects not entrusted to the government"). Here, the existence of a detailed federal regulatory scheme is used by the executive branch as a pretext for supplanting a state policy (in favor of choice in end-of-life decisionmaking) with a federal one (motivated by opposition to such choice) – despite the fact that the imposition of the preferred federal policy is wholly unrelated to any salient administrative concern entailed by management of the Controlled Substances Act. Whatever *Raich* may mean, it cannot be interpreted to mean that agency enforcement power over a comprehensive scheme of regulations can serve as a cover for *any* tendentious assertion of agency power to supplant state law, no matter how unrelated it is to the administration of the regulatory scheme enacted by Congress.

2. The means chosen by the federal government to

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[4] Further evidence suggesting that the Ashcroft Directive is not a "plainly" adapted means of implementing the CSA is the determination of Attorney General Ashcroft's predecessor, Janet Reno, that federal law does *not* authorize administrative actions like the Ashcroft Directive. *Oregon v. Ashcroft*, 368 F.3d 1118, 1123 (9th Cir. 2004) (recounting that Attorney General Reno explained in 1998 that the CSA was not "intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice" and opined that "the CSA does not authorize [the federal government] to prosecute, or to revoke DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law").

effectuate a legitimate goal must not only be necessary to the achievement of that goal, but they must also be "proper," in the sense that they cannot be otherwise inconsistent with "the letter and spirit of the [C]onstitution." *Id.*; *cf also Raich*, 125 S. Ct. at 2231 (Thomas, J., dissenting).

a. As Justice Scalia noted in *Raich*, "[c]ases such as *Printz v. United States* . . . and *New York v. United States* . . . affirm that a law is not '***proper*** for carrying into Execution the Commerce Clause' . . . '[w]hen [it] violates [a constitutional] principle of state sovereignty.'" 125 S. Ct. at 2219 (Scalia, J., concurring) (quoting *Printz v. United States,* 521 U.S. 898, 923-24 (1997) and *New York v. United States,* 505 U.S. 144, 166 (1992)) (emphasis in text of opinion).

The Ashcroft Directive violates constitutional principles of state sovereignty in at least three ways. First and most obviously, it violates Oregon's sovereign interest in regulating professional medical conduct within its borders. *Cf., e.g., Linder,* 268 U.S. at 18 ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government"); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power"). Second, the Ashcroft Directive purports to veto two state-wide democratic referenda – a fundamentally sovereign act of self-government[5] – by the fiat of a single, unelected federal bureaucrat acting outside the deliberative process of Article I decisionmaking. If approved here, that veto would not only shutter laboratories of state civic experimentation long protected by this Court, but would do so in a fashion wholly inconsistent with the explicit

[5] *Cf., e.g., Rodgers v. Fed. Trade Comm'n*, 492 F.2d 228, 230 (9th Cir. 1974) (noting that when "the people[] act[] directly through either the initiative or referendum, [they] are exercising the same power of sovereignty as that exercised by the legislature in passing laws").

constitutional restraints on federal decisionmaking (bicameralism and presentment) that discipline and check novel new federal incursions into states' sphere of sovereign legislative decisionmaking. *See, e.g., INS v. Chadha*, 462 U.S. 919, 946-51 (1983).

Third, the Ashcroft Directive trenches on constitutional principles of state sovereignty by "requiring" the Oregon State Registrar to "administer or enforce a federal regulatory program." *Printz*, 521 U.S. at 935. *Printz* left no doubt that "[t]he Federal Government may neither issue directives requiring the States to address particular problems, nor command the States' officers, or those of their political subdivisions, to administer or enforce a federal regulatory program." *Id.* The Court emphasized that "[i]t matters not whether policymaking is involved, and no case-by-case weighing of the burdens or benefits is necessary; such commands are fundamentally incompatible with our constitutional system of dual sovereignty." *Id.*

The Ashcroft Directive runs afoul of these rules. The Directive includes a provision entitled "Enforcement in Oregon," which notes that under Oregon statutory law, "an attending physician who writes a prescription for medication to end the life of a qualified patient must document the medication prescribed." 66 Fed. Reg. at 56,608 (citing 3 Or. Rev. Stat. § 127.855). The Ashcroft Directive then further notes that Oregon's Health Division must require any health care provider upon dispensing medication pursuant to the Death with Dignity Act to file a copy of the dispensing record with the Health Division. *Id.* These records, the Ashcroft Directive continues, "should contain the information necessary to determine whether those holding DEA registrations who assist suicides in accordance with Oregon law are prescribing federally controlled substances for that purpose in violation of the CSA as construed by this Memorandum[.]" *Id.* The Ashcroft Directive then conscripts the Oregon State Registrar – in defiance, of course, of the will of the majority of

Oregonians who twice endorsed Oregon's Death With Dignity Act – to either furnish the prescription dispensing records directly to the DEA or make them available to the DEA for inspection so that "appropriate administrative action" may be taken against offending physicians. *Id.* The Ashcroft Directive, therefore, enrolls the Oregon State Registrar as a low-cost federal law enforcer – again, contrary to the clearly expressed wishes of a majority of Oregonians and contrary to *Printz*, which does not permit such enrollments even where they might appear otherwise reasonable or efficient. *Cf. Printz*, 521 U.S. at 935.[6]

The Ashcroft Directive plainly violates multiple constitutional principles of state sovereignty, and for that reason is not a "proper" act in effectuation of the CSA.

b. Of course, the Constitution does not simply protect state sovereignty – it protects another, more fundamental form of "sovereignty," the liberty of the individual. *See, e.g.*, U.S. Const. amend I-IX, amend. XIV. Indeed, the protection of state sovereignty is merely an instrumental means for securing individual liberty, as this Court has recognized: "[t]he Constitution does not protect the sovereignty of States for the benefit of the States or state governments as abstract political entities, or even for the benefit of the public officials governing the States." *New York*, 505 U.S. at 181. Instead, "the Constitution divides authority between federal and state governments for the protection of individuals. State

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[6] *See* 66 Fed. Reg. at 56,608 ("Thus, it should be possible to identify the cases in which federally controlled substances are used to assist suicide in Oregon in compliance with Oregon law by obtaining reports from the Oregon State Registrar without having to review patient medical records or otherwise investigate doctors. Accordingly, implementation of this directive in Oregon should not change the DEA's current practices with regard to enforcing the CSA so as materially to increase monitoring or investigation of physicians or other health care providers or to increase review of physicians' prescribing patterns of controlled substances used for pain relief.").

sovereignty is not just an end in itself: 'Rather, federalism secures to citizens the liberties that derive from the diffusion of sovereign power.'" *Id.* (citation omitted).

Under a constitutional framework in which individual liberty is of preeminent constitutional importance, the "propriety" prong of the Necessary and Proper Clause should be interpreted to require at least as much federal attention and respect for individual liberty interests – both recognized and colorable.

In this case, there are colorable liberty interests at stake – namely, those of individuals to make end-of-life medical decisions without coercion by state bureaucrats in a distant capital. Members of this Court have recognized that those interests are neither insignificant nor without persuasive arguments for constitutional protection. *See, e.g., Vacco*, 521 U.S. at 809 (Stevens, J., concurring) (there is "room for further debate" about the scope of constitutional protection for autonomy to make end-of-life decisions); *Glucksburg*, 521 U.S. at 745 (there is a "specific [constitutional] interest in making decisions about how to confront an imminent death") (Stevens, J., concurring).

If the Necessary and Proper Clause calls for heightened attention to the needs of state sovereignty, then it should compel similarly heightened attention to the possible liberty interests implicated by this case. At a minimum, that requires the Court to apply a strong presumption in favor of the most basic *procedural* protection for disputed individual liberty interests – the pluralism, and attendant possibilities of choice, that division of authority among multiple competing sovereignties makes possible. Where, as here, federal policy would effectively destroy the heterodox policy of the sole state offering protection for a liberty interest – one that members of this Court have acknowledged may have a colorable basis for constitutional protection in some circumstances – that policy

patently violates the "propriety" prong of the Necessary and Proper Clause.

CONCLUSION

For the foregoing reasons, the judgment of the Ninth Circuit Court of Appeals should be affirmed.

Respectfully submitted,

MARK K. MOLLER
THE CATO INSTITUTE
1000 Massachusetts Ave., N.W.
Washington, D.C. 20001
(202) 842-0200

PAMELA HARRIS
(Counsel of Record)
GARRETT W. WOTKYNS
ARTHUR W.S. DUFF
LAURA DE JAAGER*
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
(202) 383-5300
**Admitted in Illinois only*

Counsel for Amicus Curiae

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ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

STATE OF OREGON, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE AMERICAN CIVIL LIBERTIES UNION AND THE ACLU OF OREGON AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

STEVEN R. SHAPIRO
The Americans Civil Liberties Union Foundation
125 Broad Street
New York, NY 10004

CHARLES F. HINKLE
ACLU Foundation of Oregon
Stoel Rives LLP
900 S.W. Fifth Avenue
Portland, OR 97204

ANDREW L. FREY
Counsel of Record
DAVID M. GOSSETT
KRISTINA SILJA BENNARD
Mayer, Brown, Rowe & Maw LLP
1909 K Street, N.W.
Washington, DC 20006
(202) 263-3000

Counsel for The American Civil Liberties Union and The ACLU of Oregon

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTEREST OF AMICI CURIAE 1

INTRODUCTION AND SUMMARY OF ARGUMENT 1

ARGUMENT 5

THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA SHOULD BE REJECTED BECAUSE IT RAISES SERIOUS CONSTITUTIONAL DOUBTS UNDER THE FOURTEENTH AMENDMENT. 5

A. Oregon's Interpretation Of The CSA, Under Which That Statute Would Permit The Continued Operation Of The DWDA, Is Clearly Reasonable. 7

B. Preventing Physicians From Prescribing Lethal Dosages Of Schedule II Medications To Individuals Who Qualify Under The DWDA Would Raise Serious Constitutional Concerns. 9

1. Oregon's DWDA is narrowly drawn and carefully applied. 10

2. Experience shows that the DWDA is, in fact, applied only in the most severe cases and is not being abused by unscrupulous doctors, incapable patients, or uncaring family members. 12

3. The DWDA — by its express terms and in practice — addresses the legitimate concerns expressed in *Glucksberg* regarding physician-assisted suicide. 14

TABLE OF CONTENTS
(continued)

Page

C. The Existence Of Extreme Pain-Relief Measures Does Not Resolve The Constitutional Problems With The Attorney General's Interpretation Of The CSA. 17

1. The right to physician-assisted suicide is grounded on more than pain relief. 20

2. Palliative care seeks to provide relief from the entire spectrum of a terminally ill patient's suffering. 21

3. Some of the alternative forms of care proposed by petitioner's amici are inconsistent with the goals of palliative care. 22

CONCLUSION 23

TABLE OF AUTHORITIES

Page(s)

Cases

Ashwander v. *Tennessee Valley Auth.*, 297 U.S. 288 (1936) 6

Crowell v. *Benson*, 285 U.S. 22 (1932) 6

Cruzan v. *Missouri Department of Health*, 497 U.S. 261 (1990) 1, 20, 23

Edward J. DeBartolo Corp. v. *Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568 (1988) 6

Gonzales v. *Raich*, 125 S. Ct. 2195 (2005) 8

Lee v. *Oregon*, 107 F.3d 1382 (9th Cir. 1997) 1, 3

Moore Ice Cream Co. v. *Rose*, 289 U.S. 373 (1933) 7

Mossman v. *Higginson*, 4 U.S. (4 Dall.) 12 (1800) 6

Murray v. *Schooner Charming Betsey*, 6 U.S. (2 Cranch) 64 (1804) 6

N.L.R.B. v. *Catholic Bishop of Chicago*, 440 U.S. 490 (1979) 6

Oregon v. *Ashcroft*, 368 F.3d 1118 (9th Cir. 2004) 2, 4, 9

Oregon v. *Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002) 4

United States v. *Clark*, 445 U.S. 23 (1980) 6, 7, 9

United States v. *Locke*, 471 U.S. 84 (1985) 7

Washington v. *Glucksberg*, 521 U.S. 702 (1997) ..... *passim*

Zadvydas v. *Davis*, 533 U.S. 678 (2001) 3, 6, 7, 9

Statutes, Regulations & Rules

Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* 2

TABLE OF AUTHORITIES
(continued)

Page(s)

Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) 8

Death with Dignity Act ("DWDA"), OR. REV. STAT. § 127.800 *et seq.* 2

OR. REV. STAT. § 127.800(12) 10

OR. REV. STAT. § 127.805(1) 10

OR. REV. STAT. § 127.810 ..... 11, 14

OR. REV. STAT. § 127.815 ..... 11, 14

OR. REV. STAT. § 127.820 ..... 11, 14

OR. REV. STAT. § 127.825 ..... 11, 15

OR. REV. STAT. § 127.830 11

OR. REV. STAT. § 127.840 ..... 11, 14

OR. REV. STAT. § 127.850 11

OR. REV. STAT. § 127.855 ..... 11, 12

OR. REV. STAT. § 127.865 12

OR. REV. STAT. § 127.880 ..... 11, 16

OR. REV. STAT. § 127.885(4) 12

MONT. CODE ANN. § 50-9-101 14

VA. CODE ANN. § 54.1-2984 14

S. 434 (SB 434-A), 72nd Leg. (Or. 2003) 16, 17

42 C.F.R. § 418.20 16

42 C.F.R. § 418.22(b) 16

42 C.F.R. § 418.24 16

Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Nov. 9, 2001) 3

TABLE OF AUTHORITIES
(continued)

Page(s)

OR. ADMIN. R. 410-142-0020 ..... 21, 22

OR. ADMIN. R. 410-142-0040(1) 15

S. Ct. Rule 37.1 4

Miscellaneous

ABC News Report, *When Medicine Clashes With the Law* (May 11, 2005) 19

Erin Hoover Barnett, *Case Marks Big Shift in Pain Policy*, OREGONIAN, Sept. 2, 1999 16

Brian Boyle, *The Oregon Death With Dignity Act: A Successful Model or a Legal Anomaly Vulnerable to Attack?*, 40 HOUS. L. REV. 1387 (2004) 12

Erwin Chemerinsky, *Raising Constitutional Doubts*, 38-Jan. TRIAL 68 (2002) 6

RONALD DWORKIN, LIFE'S DOMINION: AN ARGUMENT ABOUT ABORTION, EUTHANASIA, AND INDIVIDUAL FREEDOM (1993) 23

Growth House Inc., *Palliative Care, Professional Resources* at www.growthhouse.org/palliat.html 21

Bryan Hilliard, *Evaluating the Dissent in* State of Oregon v. Ashcroft: *Implications for the Patient-Physician Relationship and the Democratic Process*, 33 J. L. MED. & ETHICS 142 (2005) 17

H.R. Rep. No. 91-1444, reprinted in 1970 U.S.C.C.A.N. 4566 8

Letter, Attorneys General Express Concern with DEA Action and Prescription Pain Medication Policy (Jan. 19, 2005) 19

TABLE OF AUTHORITIES
(continued)

Page(s)

Ronald T. Libby, CATO Institute Policy Analysis No. 545, *Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers* (June 6, 2005) 19

Note, *The Avoidance of Constitutional Questions and the Preservation of Judicial Review: Federal Court Treatment of the New Habeas Provisions,* 111 HARV. L. REV. 1578 (1998) 6

Susan Okie, M.D., *Physician-Assisted Suicide — Oregon and Beyond*, 352:16 NEW ENG. J. MED. 1627 (April 21, 2005) 12, 13

Oregon Dep't of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (March 10, 2005) ..... *passim*

Joseph P. Pestaner, *End-of-Life Care: Forensic Medicine v. Palliative Medicine*, 31 J. L. MED. & ETHICS 365 (2003) 16

Timothy E. Quill, M.D. & Christine K. Cassel, M.D., *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138:3 ANNALS OF INTERNAL MED. 208 (Feb. 4, 2003) 13

Robert Steinbrook, *Physician-Assisted Suicide in Oregon – An Uncertain Future*, 346:6 NEW. ENG. J. MED. (Feb. 7, 2002) 13

Statement of Attorney General Reno on Oregon's Death with Dignity Act (June 5, 1998) 9

Adrian Vermeule, *Saving Constructions*, 85 GEO. L. J. 1945 (1997) 6

Beth Packman Weinman, *Freedom From Pain*, 24 J. LEGAL MED. 495 (2003) 21

TABLE OF AUTHORITIES
(continued)

Page(s)

Washington v. *Glucksberg*, Brief for the United States as Amicus Curiae, 1996 WL 663185 (Nov. 12, 1996) 20

BRIEF OF THE AMERICAN CIVIL LIBERTIES UNION AND THE ACLU OF OREGON AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

INTEREST OF AMICI CURIAE

The American Civil Liberties Union ("ACLU") is a nationwide, nonprofit, nonpartisan organization with more than 400,000 members dedicated to the principles of liberty and equality embodied in the Constitution and this nation's civil rights laws. The ACLU of Oregon is one of its statewide affiliates. The personal autonomy issues raised by this case and discussed in this brief have been central to the ACLU's concerns for many years. Of particular note, the ACLU represented the petitioner in *Cruzan* v. *Missouri Department of Health*, 497 U.S. 261 (1990), and submitted an amicus brief in *Washington* v. *Glucksberg*, 521 U.S. 702 (1997). The ACLU of Oregon supported passage of Oregon's Death with Dignity Act, directly represented Intervenors-Defendants Levin and Schuck in a constitutional challenge to the statute (*Lee* v. *Oregon*, 107 F.3d 1382 (9th Cir. 1997)), and submitted an amicus brief in the district court supporting the state's defense of the statute.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

In *Washington* v. *Glucksberg*, 521 U.S. 702 (1997), the Court declined to strike down a statute prohibiting physician-assisted suicide as facially unconstitutional, but left open the possibility that there could be situations in which blocking a terminally ill, mentally competent patient from obtaining pre-

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[1] Pursuant to Rule 37.6, amici affirms that no counsel for a party authored this brief in whole or in part and that no person other than amici and its counsel made a monetary contribution to its preparation or submission. The parties' letters consenting to the filing of this brief have been filed with the Clerk's office.

scription drugs to end his or her life would transgress the Constitution's guarantee of liberty and privacy. Although the various opinions in *Glucksberg* differed as to the exact contours of that constitutional boundary, taken together these opinions provide a general outline of the circumstances in which obstructing access to physician-assisted suicide would have constitutional implications.

Oregon's Death with Dignity Act ("DWDA"), Or. Rev. Stat. § 127.800 *et seq.*, fits that outline. The carefully drawn statute has built-in safeguards against abuse, ensuring that only patients whose claim to physician-assisted suicide is at its constitutional zenith may invoke the statute's provisions. This case, however, does not require the Court to resolve whether impeding terminally ill Oregonians from making their own end-of-life decisions under the DWDA would in fact violate the liberty and privacy interests protected by the Fourteenth Amendment. It is enough that the Attorney General's construction of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.*, which would effectively nullify the DWDA, raises serious constitutional doubts under the Fourteenth Amendment.[2] When the Court reads the CSA

[2] While the Ashcroft Directive purports to leave Oregon's DWDA intact — because it only prohibits the use of Schedule II narcotics for physician-assisted suicide — the Directive blocks access to what physicians consider to be the safest and most effective means of ending one's life. See, *e.g.*, *Oregon* v. *Ashcroft*, 368 F.3d 1118, 1123 n.5 (9th Cir. 2004). Indeed, 204 of the 208 individuals who have ended their lives under the DWDA used Schedule II drugs. See Oregon Dep't of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act*, at 24 (Table 4) (March 10, 2005), available at http://egov.oregon.gov/DHS/ph/pas/docs/year7pdf. It is at best a cruel rejoinder that under the Ashcroft Directive terminally ill individuals still would have available to them other, less effective, less safe, and, perhaps, less gentle measures to end their lives. See, *e.g.*, *Oregon* v. *Ashcroft*, 368 F.3d at 1135 (Wallace, J., dissenting) ("Oregon physicians may continue to assist suicide by other means" such as with "carbon monoxide"); Amicus Br. of Int'l Task Force on Euthanasia and Assisted Suicide, at 7 ("A physician could write a prescription for the type of assisted suicide appliance made from plastic tubing to be used with substances that are not federally controlled.").

"in the light of the Constitution's demands" (*Zadvydas* v. *Davis*, 533 U.S. 678, 689 (2001)), as it must, it will see that only a construction that does not undermine Oregon's DWDA passes constitutional muster. Accordingly, the Attorney General's reading of the CSA must be rejected.

The DWDA permits physicians to prescribe drugs that will enable certain terminally ill, mentally competent Oregonians to end their lives. See pp. 10-12, *infra*. The statute has already withstood direct constitutional challenge (*Lee* v. *Oregon*, 107 F.3d 1382 (9th Cir. 1997)) and a later anti-DWDA ballot measure.[3] This case arose when Attorney General Ashcroft adopted a policy in 2001 designed to thwart the decision of Oregon voters to permit physician-assisted suicide under carefully controlled circumstances. Rejecting his predecessor's reading of the CSA — a statute designed to counter drug trafficking and diversion — he determined that the use of Schedule II prescription drugs, *i.e.*, those overwhelmingly used by terminally ill individuals under the DWDA, lacked the "legitimate medical purpose" required by the CSA. See Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Nov. 9, 2001) (hereinafter "Ashcroft Directive"). Thus, the Attorney General's reading of the CSA allows him not only to prosecute any physician who writes a DWDA prescription in accordance with Oregon's law, but also to revoke that physician's ability to write any prescriptions for substances regulated by the CSA.

[3] In 1997, Oregon voters convincingly rejected a ballot measure that would have repealed the DWDA.

Oregon brought suit in federal court to block enforcement of the Ashcroft Directive.[4] The U.S. District Court for the District of Oregon permanently enjoined the Ashcroft Directive, finding that nothing in "the CSA * * * demonstrates or even suggests that Congress intended to delegate to the Attorney General or the [Drug Enforcement Administration ("DEA")] the authority to decide, as a matter of national policy, a question of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice." *Oregon* v. *Ashcroft*, 192 F. Supp. 2d 1077, 1089 (D. Or. 2002).

On appeal, the Ninth Circuit affirmed, also grounding its decision on interpretation of the CSA. *Oregon* v. *Ashcroft*, 368 F.3d 1118 (9th Cir. 2004). The court held that "[t]he Ashcroft Directive is invalid because Congress has provided no indication * * * that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide." *Id.* at 1125. In the course of analyzing the case, the Ninth Circuit identified a potential constitutional problem with the Attorney General's reading of the CSA: the Ashcroft Directive — "by encroaching on state authority to regulate medical practice" — might exceed Congress's authority under the Commerce Clause, from which Congress' authority to enact the CSA is derived. *Ibid.* Absent an "unmistakably clear expression of intent to alter the usual constitutional balance," the court held that it was bound to interpret the CSA "to preserve rather than destroy the States' substantial sovereign powers." *Ibid.* (quotation marks omitted).

In our view, the Attorney General's interpretation of the CSA raises another substantial constitutional issue that provides additional grounds for affirming the decision below. See S. Ct. Rule 37.1. Specifically, the Ashcroft Directive

[4] Later, a group of terminally ill Oregonians, a physician and a pharmacist moved to intervene.

raises serious constitutional problems in light of the suggestion by a majority of the *Glucksberg* Court that the Fourteenth Amendment may well protect the right of mentally competent, terminally ill patients — who may be experiencing great suffering — to physician-assisted suicide with safe and effective prescription drugs in order to ease their suffering and to control the circumstances of their imminent death.

Under well-established principles of statutory construction, this Court should reject an interpretation of the CSA that gives rise to such constitutional doubts. See Part A, *infra*. As set forth more fully below, the DWDA is a narrowly drawn, comprehensive statute designed to permit physician-assisted suicide for only those mentally competent, terminally ill individuals who have the most compelling constitutional claim to protection under the Fourteenth Amendment. See Part B, *infra*. And as we explain in Part C, *infra*, the existence of extreme pain-relief measures does nothing to lessen the constitutional doubt that arises from denying these individuals the shelter they seek in the DWDA.

Although this case does not itself present a direct constitutional challenge to the Ashcroft Directive, there is a reasonable interpretation of the CSA that will enable the Court to avoid having to confront that constitutional question in the future. Given the strained nature of the Attorney General's interpretation of the CSA, that is clearly the correct outcome here.

ARGUMENT

THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA SHOULD BE REJECTED BECAUSE IT RAISES SERIOUS CONSTITUTIONAL DOUBTS UNDER THE FOURTEENTH AMENDMENT.

When interpreting federal statutes, this Court has long adhered to the view that, whenever reasonably possible, a construction should be adopted that will avoid the need to

decide constitutional questions. *E.g.*, *Ashwander* v. *Tennessee Valley Auth.*, 297 U.S. 288, 341 (1936) (Brandeis, J., concurring). Accordingly, it is a "'cardinal principle' of statutory interpretation" that "'th[e] Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided.'" *Zadvydas*, 533 U.S. at 689 (quoting *Crowell* v. *Benson*, 285 U.S. 22, 62 (1932)). Accord *Edward J. DeBartolo Corp.* v. *Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); *United States* v. *Clark*, 445 U.S. 23, 31 (1980). This principle of statutory interpretation has a long pedigree of guarding against erosion of individual constitutional rights, including religious liberty (*N.L.R.B.* v. *Catholic Bishop of Chicago*, 440 U.S. 490, 507 (1979)), free speech (*DeBartolo Corp.*, 485 U.S. at 575-576), due process (*Zadvydas*, 533 U.S. at 682, 690), and equal protection (*Clark*, 445 U.S. at 33-34).[5]

In order to apply the doctrine of constitutional doubt, the Court need not decide that the interpretation of the CSA contained in the Ashcroft Directive would, in fact, lead that statute to be unconstitutional — only that such an interpretation would "raise[] a serious doubt as to [the statute's] constitutionality." *Zadvydas*, 533 U.S. at 689 (quotation marks omitted).[6] So long as one interpretation of the statute is

[5] The doctrine of constitutional doubt is well established. Some commentators trace it back to the earliest days of the Republic. *E.g.*, Note, *The Avoidance of Constitutional Questions and the Preservation of Judicial Review: Federal Court Treatment of the New Habeas Provisions*, 111 HARV. L. REV. 1578, 1585 (1998) (tracing doctrine back to *Murray* v. *Schooner Charming Betsey*, 6 U.S. (2 Cranch) 64 (1804)); Adrian Vermeule, *Saving Constructions*, 85 GEO. L. J. 1945, 1948 (1997) (tracing doctrine back to *Mossman* v. *Higginson*, 4 U.S. (4 Dall.) 12 (1800)).

[6] See also Erwin Chemerinsky, *Raising Constitutional Doubts*, 38-Jan. TRIAL 68, 70 (2002) (to create constitutional doubt, "a lawyer need not convince a court that a law is unconstitutional,"

reasonable — and, as we discuss in Part A, Oregon's interpretation of the CSA is in fact persuasive — courts must avoid any other interpretation that may raise a significant constitutional problem. As we demonstrate in Part B, the interpretation of the CSA contained in the Ashcroft Directive clearly threatens to transgress constitutional bounds, and thus must be rejected.

A. Oregon's Interpretation Of The CSA, Under Which That Statute Would Permit The Continued Operation Of The DWDA, Is Clearly Reasonable.

The first stage of a constitutional-doubt analysis is to determine whether there is a plausible reading of a statute that raises no constitutional issue. While a court cannot "press statutory construction 'to the point of disingenuous evasion' * * * to avoid a constitutional question" (*United States* v. *Locke*, 471 U.S. 84, 96 (1985) (quoting *Moore Ice Cream Co.* v. *Rose*, 289 U.S. 373, 379 (1933))), it should not reach constitutional questions that a plausible reading of the statute would avoid. *Zadvydas*, 533 U.S. at 689.

There can be little doubt that Oregon's reading of the CSA, which permits the continued operation of the DWDA, is — at the very least — "fairly possible" (*id.* at 689 (quotation marks omitted)). Oregon's reading is "not at odds with fundamental legislative purposes" and "appears fair and reasonable in light of the language, purpose, and history" of the CSA. *Clark*, 445 U.S. at 31. And certainly nothing in the text of the CSA *compels* the interpretation of "legitimate medical purpose" asserted by the Attorney General. See *Locke*, 471 U.S. at 96 (declining to apply doctrine of constitutional doubt where statutory language did not permit an interpretation that "avoid[ed] a constitutional question"). The use Oregon

but rather must "only persuade the court that there are important constitutional issues with uncertain resolutions").

makes of physicians in the DWDA scheme, described more fully below, is important to assure that the carefully circumscribed limitations on access to the Act's protections are effectively enforced; non-physicians simply could not administer the statute's safeguards as competently. It takes no linguistic contortions to find that the role assumed by physicians under Oregon's scheme serves a "legitimate medical purpose."

This conclusion is resoundingly reaffirmed when consideration is give to the congressional goals in enacting the CSA. That statute unquestionably was designed to prevent drug abuse and trafficking — not to prevent physicians from prescribing drugs to help their patients deal with the physical pain and mental anguish of advanced terminal illness, where no link to trafficking or abuse is even suggested. The statute itself explains that its purpose is to "increase[] research into, and prevention of, drug abuse and drug dependence * * * and to strengthen existing law enforcement authority in the field of drug abuse." Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). Similarly, the House Report accompanying the Act explained that "[t]his legislation is designed to deal in comprehensive fashion with the growing menace of drug abuse in the United States." H.R. Rep. No. 91-1444, reprinted in 1970 U.S.C.C.A.N. 4566, 4567. And this Court recognized just last Term that "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales* v. *Raich*, 125 S. Ct. 2195, 2203 (2005).

In fact, even the Attorney General does not — indeed, cannot — point to any language in the CSA indicating that the statute was meant to bar drug use of the kind authorized by the DWDA (see U.S. Br. at 18-20). His amici, too, concede that the legislative history of the CSA contains not one hint that in enacting that legislation, Congress had in mind —

let alone sought to restrict — physician-assisted suicide. See, *e.g.*, Amicus Br. of Sen. R. Santorum, et al., at 3, 21-22.[7]

Thus, it is no surprise that Attorney General Reno determined that the CSA did not preclude the continued operation of Oregon's DWDA because "[t]he particular drug abuse that Congress sought to prevent was that deriving from the drug's 'stimulant, depressive, or hallucinogenic effect on the central nervous system.'" Stmt. of Attorney General Reno on Oregon's Death with Dignity Act (June 5, 1998), available at http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html (quoting 21 U.S.C. § 811(f)).

In short, reading the CSA to avoid interference with the DWDA is eminently reasonable — and, we submit, correct. Most importantly, however, unlike the Ashcroft Directive, Oregon's interpretation "avoids a serious constitutional question" (*Clark*, 445 U.S. at 31), the issue to which we now turn.

B. Preventing Physicians From Prescribing Lethal Dosages Of Schedule II Medications To Individuals Who Qualify Under The DWDA Would Raise Serious Constitutional Concerns.

Notwithstanding differing views on the scope and strength of substantive due process, this Court has recognized that, under certain circumstances, a patient's claim to physician-assisted suicide could assume constitutional dimensions. Although in *Washington* v. *Glucksberg*, 521 U.S. 702 (1997), this Court held that there was no general Fourteenth Amendment right to physician-assisted suicide, the Court explicitly left open the possibility that a mentally competent

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[7] A more detailed discussion of the text, history, and purpose of the CSA appears in the Ninth Circuit's opinion (368 F.3d at 1127-1129) and, we presume, in the respondents' briefs. This truncated discussion suffices here in that the doctrine of constitutional doubt requires only a showing that Oregon's reading of the CSA is plausible. *E.g.*, *Zadvydas*, 533 U.S. at 689.

individual — who may be experiencing great suffering — may have a constitutionally cognizable interest in controlling the circumstances of her death by means of physician-assisted suicide with scheduled narcotics. *Id.* at 735 n.24, 736-737 (O'Connor, J., concurring), 751-752 (Stevens, J., concurring in the judgment), 782 (Souter, J., concurring in the judgment), 789 (Ginsburg, J., concurring in the judgment), 792 (Breyer, J., concurring in the judgment).

It is now eight years after *Glucksberg* and eight years into Oregon's experiment with the DWDA. In marked contrast to *Glucksberg*, in which the contours of and limits on the asserted right to physician-assisted suicide were unknown, here, a terminally ill individual must clear several specific and carefully constructed hurdles before qualifying under the DWDA. These strict requirements insure that only mentally competent individuals in the most dire situations are eligible. A majority of the Court in *Glucksberg* strongly suggested that circumstances like those facing patients who meet DWDA's requirements would, in fact, give rise to constitutional protection. See pp. 14-17, *infra*.

1. Oregon's DWDA is narrowly drawn and carefully applied.

The DWDA's built-in safeguards ensure that only patients in constitutionally compelling circumstances are permitted to invoke the statute. For example:

- Among other qualifications, the patient must be a terminally ill Oregon resident with a life expectancy of less than six months (OR. REV. STAT. §§ 127.800(12), 127.805(1)),[8] and must be capable of

[8] A patient is "terminally ill" if he or she has "an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months." Or. Rev. Stat. § 127.800(12).

making and communicating health care decisions (*id.* § 127.815).

- To ensure that an individual has fully considered her decision, she must make two oral requests for a lethal prescription to her physician, separated by at least 15 days. *Id.* § 127.840.
- The patient must also provide a written request that is signed in the presence of two witnesses — at least one of whom is not related to the patient — who will attest that the patient is competent and acting voluntarily (*id.* §§ 127.810, 127.840).
- The physician must inform the patient of the available alternatives to assisted suicide, such as hospice care. *Id.* §§ 127.815(1)(c)(E), 127.830.
- A second physician must confirm the patient's diagnosis and prognosis, as well as the first physician's determination of the patient's mental competence. *Id.* §§ 127.815(1)(d), 127.820.
- If either physician has any doubts about a patient's mental state, he or she must refer the patient for a psychiatric or psychological evaluation. *Id.* § 127.825.
- There is then another 48-hour waiting period after the patient's written request before the physician actually may write the prescription. *Id.* § 127.850.
- The patient must be capable of taking the medication orally — no one else is permitted to administer the prescription. *Id.* § 127.880.
- Oregon closely monitors the DWDA. Physicians must report to the Oregon Health Division all prescriptions that they write for lethal medication and describe the characteristics of the patient. *Id.* §§ 127.815(1)(j),

127.855.[9] The state collects this data and publishes it in an annual report. *Id.* § 127.865. It is intended that detailed information regarding the use of the DWDA be abundant and accessible.

In short, the DWDA establishes a comprehensive framework designed to permit only patients facing the greatest hardships to invoke its provisions.

2. ***Experience shows that the DWDA is, in fact, applied only in the most severe cases and is not being abused by unscrupulous doctors, incapable patients, or uncaring family members.***

Oregon's experience with the DWDA has proven to be quite at odds with the oft-repeated and familiar parade of horribles one hears from opponents of physician-assisted suicide. The data gathered by Oregon demonstrates that "[t]he law has not had the dire social consequences that some opponents predicted." Susan Okie, M.D., *Physician-Assisted Suicide — Oregon and Beyond*, 352:16 NEW ENG. J. MED. 1627, 1628 (April 21, 2005). In fact, "[t]here is no evidence that it has been used to coerce elderly, poor, or depressed patients to end their lives, nor has it caused any significant migration of terminally ill people to Oregon." *Ibid.* See also Brian Boyle, *The Oregon Death With Dignity Act: A Successful Model or a Legal Anomaly Vulnerable to Attack?*, 40 HOUS. L. REV. 1387, 1388 (2004) (noting that DWDA "has operated relatively quietly and modestly since its inception in 1997") (footnote omitted). The data thus belie the doomsday prophesies made when the DWDA took effect.

Between 1998 and 2004, 326 patients received prescriptions for drugs intended to hasten their deaths; 208 of those individuals, or 64%, actually used them. See Oregon Dep't of

[9] Doctors are under no obligation to write a lethal prescription. OR. REV. STAT. § 127.885(4).

Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (March 10, 2005), available at http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf (hereinafter "*Seventh Annual Report*"). Of the 208 who ingested their prescription, 86% of them were enrolled in hospice care (*id.* at 24 (Table 4)), and, remarkably, 99% had some form of health insurance at the time of their death. *Ibid.*

Moreover, it is clear that robust end-of-life care and physician-assisted suicide are not mutually exclusive. Since the DWDA took effect, commentators have noted "[e]vidence of concomitant improvements in end-of-life care in Oregon," including "increased hospice referrals, morphine prescription per capita among the highest in the United States," and "increased physician attendance at palliative care conferences." Timothy E. Quill, M.D. & Christine K. Cassel, M.D., *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138:3 ANNALS OF INTERNAL MED. 208, 209 (Feb. 4, 2003). Accord Robert Steinbrook, *Physician-Assisted Suicide in Oregon – An Uncertain Future*, 346:6 NEW. ENG. J. MED. (Feb. 7, 2002), available at 2002 WLNR 5896 ("there is evidence that the overall quality of care for dying patients in the state has improved"; "[b]etween 1997 and 2000, morphine use increased by about 50 percent in Oregon").

Indeed, after just two years of DWDA's existence, 76% of Oregon physicians who cared for terminally ill patients reported having improved their knowledge of pain treatment and their recognition of psychiatric disorders such as depression. *Seventh Annual Report*, at 17; Okie, *supra*, at 1629. And, as noted above, Oregon physicians now refer patients to hospice *more* frequently than before enactment of the DWDA. *Seventh Annual Report*, at 17; Okie, *supra*, at 1629; Quill & Cassel, *supra*, at 209.

3. *The DWDA — by its express terms and in practice — addresses the legitimate concerns expressed in* Glucksberg *regarding physician-assisted suicide.*

Although the opinions in *Glucksberg* provided varying degrees of detail about the factors that could give rise to a constitutional right to physician-assisted suicide, certain concerns permeate every Justice's opinion in that case. The DWDA guards against these potential pitfalls and establishes a comprehensive framework that not only permits careful analysis but also ensures that "recognizing [the] due process right" of individuals covered by DWDA would not "leave a court with no principled basis to avoid recognizing another." *Glucksberg*, 521 U.S. at 785 (Souter, J., concurring in the judgment).

a. Oregon's law includes multiple safeguards to ensure that "those who are not truly competent or facing imminent death, or those whose decisions to hasten death would not truly be voluntary," cannot invoke its provisions. *Id.* at 737 (O'Connor, J., concurring).

As outlined above, the DWDA requires a terminally ill patient to make his or her request for a lethal prescription multiple times over at least a 15-day period and in the presence of two witnesses. OR. REV. STAT. §§ 127.810, 127.840. A second independent physician must confirm the patient's diagnosis, prognosis, and mental competence to make health care decisions. *Id.* §§ 127.815(1)(d), 127.820.[10] If either physician suspects that a patient is suffering from depression or other psychiatric impairments, they must refer the patient to a mental health expert for analysis. *Id.* § 127.825. Thus, the DWDA is able to "strike the proper balance between the interests of the terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring).

[10] Of course, a doctor's informed judgment as to a terminally ill patient's life expectancy cannot be made with 100% certainty. However, the DWDA guards against abuse by requiring two physicians to agree on a patient's diagnosis and prognosis. Moreover, the term "terminal condition" is used (and defined) in "living will" statutes in effect in most states. *E.g.*, VA. CODE ANN. § 54.1-2984; MONT. CODE ANN. § 50-9-101. So, while the term is not free from difficulty, it has proved workable.

In addition, only the "knowing and responsible" qualify under the DWDA. *Glucksberg*, 521 U.S. at 787 (Souter, J., concurring in the judgment). Because physicians are required to advise patients about other end-of-life options, including comfort care and hospice, the DWDA covers only "individual[s] adequately informed of the[ir] care alternatives." *Id.* at 748 (Stevens, J., concurring in the judgment). For these informed and competent individuals who "might make a rational choice for assisted suicide," "the State's interest in preventing potential abuse and mistake is only minimally implicated." *Ibid.*

Further lessening any fears that a terminally ill patient may face coercion or undue pressure — or, as the Attorney General's amici suggest, "a duty to die" (*e.g.*, Amicus Br. of Focus on the Family, at 23) — it is important to note that *all* Oregon residents have access to hospice care, regardless of their ability to pay,[11] and Medicare covers hospice for pa-

[11] Oregon's Health Plan covers hospice care (OR. ADMIN. R. 410-142-0040(1)), and "Oregon's hospices support universal access to hospice care [and] will not turn dying Oregonians and their families away because they cannot pay for its services." Oregon Hospice Ass'n, at http://www.oregonhospice.org/endoflifecare_legal.htm (last visited July 14, 2005). See also Central Oregon Home Health & Hospice (will "not refuse care to anyone for lack of ability to pay"), at http://www.cohospice.org/hospicecare.htm (last visited July 10, 2005); Providence Hospice (same), at

tients with less than six months to live (42 C.F.R. §§ 418.20, 418.22(b), 418.24). Thus, worries about being unable to afford end-of-life-care or about burdening family members need not affect the decisions of terminally ill patients. Finally, only the patient herself may administer the drug — no doctor or family member may assist. OR. REV. STAT. § 127.880.

b. There is also no indication that the DWDA has disproportionately impacted vulnerable groups in Oregon. In fact, quite the opposite: "[a] higher level of education was strongly associated with the use of PAS" and those who invoked the DWDA were on average younger than those in Oregon dying of natural causes. *Seventh Annual Report*, at 13, 22 (Table 2). Almost an equal number of men and women have used the DWDA. *Ibid.* And, as noted above, 99% of patients who availed themselves of the DWDA had some form of health insurance at the time of their death, and 86% were receiving hospice care. See page 13, *supra*.

c. Moreover, there is no indication that the DWDA has impeded advancements in end-of-life and palliative care. To the contrary, since 1997 *more* terminally-ill Oregonians have been referred to hospice, doctors have increased their knowledge of palliative care options, and prescriptions for pain relief medications have increased. See page 13, *supra*. Oregon is also one of the few states to begin disciplining doctors for the *under*-treatment of pain. See Joseph P. Pestaner, *End-of-Life Care: Forensic Medicine v. Palliative Medicine*, 31 J. L. MED. & ETHICS 365, 369 (2003); Erin Hoover Barnett, *Case Marks Big Shift in Pain Policy*, OREGONIAN, Sept. 2, 1999, at A1.[12]

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http://www.providence.org/Oregon/Programs_and_Services/Hospice/about.htm (last visited July 14, 2005)).

[12] Along these lines, in 2003, Oregon passed a measure that requires the state's health-professional regulatory boards to "encourage the development of state-of-the-art multidisciplinary pain management services and the availability of these services to the public." S. 434 (S.B. 434-A), 72nd Leg. (Or. 2003).

* * * * *

As Justice Souter recognized in *Glucksberg*, "events could overtake [the Court's] assumptions, as experimentation in some jurisdictions confirm[] or discredit[] the concerns about progression from assisted suicide to euthanasia." 521 U.S. at 787 (Souter, J., concurring in the judgment). Eight years of experience suggests that the DWDA has adequately addressed these fears. Unlike *Glucksberg* — where the particulars of the asserted right were undefined and it was unknown how a regime of physician-assisted suicide would operate in practice — here the Court has before it an actual statute that establishes defined, detailed boundaries, that has been in use since 1997, and about which detailed data is available for evaluation.[13] In this context, the constitutional claim to a right of physician-assisted suicide is at its zenith. Any interpretation of the CSA that interferes with such a right should be avoided if at all possible.

C. The Existence Of Extreme Pain-Relief Measures Does Not Resolve The Constitutional Problems With The Attorney General's Interpretation Of The CSA.

In an apparent, though unspoken, attempt to convince this Court that *Glucksberg* was wrong to suggest that there might, in certain cases, be a constitutionally protected right to physician-assisted suicide — and, as a result, that our constitutional doubt argument is irrelevant — several of petitioners'

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[13] See Bryan Hilliard, *Evaluating the Dissent in* State of Oregon v. Ashcroft: *Implications for the Patient-Physician Relationship and the Democratic Process*, 33 J. L. MED. & ETHICS 142, 144 (2005) ("The Oregon Act details quite explicitly the requirements patients have to meet and the responsibilities physicians must fulfill in order for a prescription to be written and for death to be hastened.").

amici assert that advances in pain-relief treatments have, in essence, mooted any right to physician-assisted suicide in any circumstance. That argument does not withstand scrutiny.

In particular, petitioners' amici argue that the existence of measures to ameliorate the pain of terminally ill individuals in almost all instances demonstrates that the DWDA is not necessary to ensure those individuals a pain-free death. *E.g.*, Amicus Br. of Am. United for Life, at 5-10; Amicus Br. of Physicians for Compassionate Care Educ. Found., at 7-9; Amicus Br. of U.S. Conference of Catholic Bishops, et al., at 12-24. From this premise, the amici would presumably argue that even if there were a right to a pain-free death protected by the Fourteenth Amendment (see *Glucksberg*, 521 U.S. at 737-738 (O'Connor, J., concurring)), the availability of pain relief for all terminally ill individuals negates any constitutional claim to physician-assisted suicide that patients eligible for the DWDA might otherwise have.

This is a myopic view of an individual's final days and fails to take into account the mental, emotional, and spiritual hardships that attend one's exit from this world — any one of which could lead a patient to seek the relief provided by the DWDA. A terminally ill patient's constitutional claim to invoke the DWDA is based on more than his or her interest in a pain-free death. Indeed, the majority of Oregonians who have used the DWDA have given as their reasons for doing so loss of autonomy and loss of dignity. *Seventh Annual Report*, at 15, 24 (Table 4).

Members of this Court have similarly rejected a single-minded focus on physical pain. *Glucksberg*, 521 U.S. at 743 (Stevens, J., concurring in the judgment); *id.* at 779, 781 (Souter, J., concurring in the judgment); *id.* at 790 (Breyer, J., concurring in the judgment). And, a majority of the Court has implicitly recognized a right to palliative care (521 U.S. at 737-738 (O'Connor, J., concurring)) — of which pain-

relief is only one facet. The existence of the range of pain-relief measures identified by amici — some of which reasonable and thoughtful individuals would find to be outright repugnant, as we explain below — therefore does not remove the constitutional doubt engendered by the Ashcroft Directive. For the same reasons, the fact that the Attorney General would still permit physicians to prescribe "sufficient dosages of pain medication necessary to eliminate or alleviate pain" (U.S. Br. at 8 n.5) does not save his reading of the CSA.[14]

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[14] Moreover, the government's assertion in this regard rings hollow in light of the DEA's current practice of targeting for investigation and prosecution doctors who prescribe opiates for treatment of chronic pain. Commentators have referred to this practice as "[t]he DEA's war on prescription painkillers," and attribute to it a worsening of the already widespread problem of undertreated or untreated chronic pain. See, *e.g.*, Ronald T. Libby, CATO Institute Policy Analysis No. 545, *Treating Doctors as Drug Dealers: The DEA's War on Prescription Painkillers* (June 6, 2005), available at http://www.cato.org/pub_display.php?pub_id=3778; ABC News Report, *When Medicine Clashes With the Law* (May 11, 2005), available at http://abcnews.go.com/Health/PainManagement/story?id=749207&page=1. Relying upon the very same reading of the CSA's language that is at issue in this case — the requirement that scheduled narcotics be prescribed only for a "legitimate medical purpose" in the "usual course of professional practice" — the federal government has waged a nationwide campaign against doctors specializing in pain treatment — prosecuting 50 last year and 42 thus far this year — which has significantly reduced the availability of pain medication to chronic pain patients. Recently, the National Association of Attorneys General ("NAAG") sent a letter, signed by 31 Attorneys General, to the head of the DEA expressing concern about the chilling effect of DEA's enforcement policies on the willingness of physicians to treat patients who are in pain. Letter, Attorneys General Express Concern with DEA Action and Prescription Pain Medication Policy (Jan. 19, 2005), available at http://www.naag.org/news/pdf/so-20050119-prescription-pain-med.pdf.

1. The right to physician-assisted suicide is grounded on more than pain relief.

In *Glucksberg*, members of this Court recognized that a right to assisted suicide could be based on *more* than one's liberty or privacy interest in a pain-free death. 521 U.S. at 743 (Stevens, J., concurring in the judgment); *id.* at 779, 781 (Souter, J., concurring in the judgment); *id.* at 790 (Breyer, J., concurring in the judgment). A dying individual's basic "freedom" includes an "interest in dignity, and in determining the character of the memories that will survive long after her death." *Id.* at 743 (Stevens, J., concurring in the judgment). This kind of "[p]ersonal control over the manner of death" (*id.* at 790 (Breyer, J., concurring in the judgment)) is an essential component of one's right to die with dignity. See also *Cruzan* v. *Missouri Dep't of Health*, 497 U.S. 261, 287 (1990) (O'Connor, J. concurring) ("our notions of liberty are inextricably entwined with our idea of *** self-determination").

As the United States itself recognized in its amicus brief in *Glucksberg*,

> a competent, terminally ill adult has a constitutionally cognizable liberty interest in avoiding the kind of suffering experienced by the plaintiffs in this case. *That liberty interest encompasses an interest in avoiding not only severe physical pain, but also the despair and distress that comes from physical deterioration and the inability to control basic bodily or mental functions in the terminal state of an illness.*

U.S. Amicus Br. in *Washington* v. *Glucksberg*, 1996 WL 663185, at *8 (Nov. 12, 1996) (emphasis added).

Indeed, "[t]he choice between life and death is a deeply personal decision." *Cruzan*, 497 U.S. at 281. Thus, access to pain-relief measures, while vital, does not end the inquiry into the constitutional protections afforded to the terminally

ill individuals who qualify for the DWDA. As such, it does not render the Attorney General's interpretation of the CSA any less constitutionally suspect.

2. Palliative care seeks to provide relief from the entire spectrum of a terminally ill patient's suffering.

A majority of the Court in *Glucksberg* implicitly recognized a constitutional right for terminally ill individuals to receive palliative care to ease their suffering, even if that care would hasten death. 521 U.S. at 737-738 (O'Connor, J., concurring). As anyone who has experienced emotional hardship knows, however, suffering can be more than just physical pain. It also includes "the despair that accompanies physical deterioration and a loss of control of basic bodily and mental functions." *Id.* at 736 (O'Connor, J., concurring).

In recognition of this reality, palliative care encompasses *more* than just pain management — rather, it is meant to ensure that one has a gentle, dignified death. See Growth House Inc., *Palliative Care, Professional Resources* at www.growthhouse.org/palliat.html (last visited July 14, 2005) ("Palliative care, also called comfort care, is primarily directed at providing relief to a terminally-ill person through symptom management and pain management. The goal is not to cure, but to provide comfort and maintain the highest possible quality of life for as long as life remains.").

"Well-rounded palliative care programs also address mental and spiritual needs" of the patient. *Id.* Accord Beth Packman Weinman, *Freedom From Pain*, 24 J. LEGAL MED. 495, 517 (2003) ("palliative care encompasses much more than simply pain management"); OR. ADMIN. R. 410-142-0020(23) (Oregon Dep't of Human Servs., Hospice Services Rulebook) (defining "Palliative Services" as "[c]omfort services of intervention that focus primarily on reduction or abatement of the physical, psychosocial and spiritual symptoms of terminal illness").

The hospice care movement also regards control of physical pain as but one part of its mission of supporting terminally ill patients; thus, hospice care also includes "services provided to meet the physical, psychosocial, spiritual and other special needs of the patient/family unit during the final stages of illness." OR. ADMIN. R. 410-142-0020(18) (Oregon Dep't of Human Servs., Hospice Services Rulebook).

*3. **Some of the alternative forms of care proposed by petitioner's amici are inconsistent with the goals of palliative care.***

As Justice Souter wrote in *Glucksberg*, terminally ill individuals often seek

> not only an end to pain (which they might [obtain], although perhaps at the price of stupor), but an end to their short remaining lives with a dignity that they believe[] would be denied them by powerful pain medication, as well as by their consciousness of dependency and helplessness as they approached death.

521 U.S. at 779 (Souter, J., concurring in the judgment).

The palliative care "options" proposed by petitioners' amici might address the physical pain a terminally ill patient can experience, but many of those "options" ignore the other purposes of palliative care — particularly insuring a gentle and dignified death. Extreme, uncomfortable, and/or invasive palliative measures such as "sedation to a sleep-like state," "surgically denervat[ing] painful areas," "anesthetic interventions to block nerve transmission" (Amicus Br. of Am. United for Life, at 9 & n.17), and "spinal infusion pumps" (Amicus Br. of Physicians for Compassionate Care Educ. Found., at 8), might render a terminally ill patient pain-free, but at the cost of eviscerating the last bit of liberty, privacy, and dignity that patient has in his final days.

Even less drastic means of pain relief carry with them potentially undesirable side effects that a patient reasonably

might wish to avoid experiencing in his or her final days. Whether it is terminal sedation, surgery to cut one's nerves, or simply large doses of strong pain medication that affect patients' mental and physical processes, there must come a point at which terminally ill individuals can decline these measures that "burden[] [their] liberty, dignity, and freedom to determine the course of [their] own treatment" (*Cruzan*, 497 U.S. at 289 (O'Connor, J., concurring)), without, as a consequence, losing all means of escaping their suffering and experiencing a gentle quitting of life. "Making someone die in a way that others approve, but he believes a horrifying contradiction of his life, is a devastating, odious form of tyranny." RONALD DWORKIN, LIFE'S DOMINION: AN ARGUMENT ABOUT ABORTION, EUTHANASIA, AND INDIVIDUAL FREEDOM 217 (1993).

"How [a person] dies will affect how that life is remembered." *Cruzan*, 497 U.S. at 344 (Stevens, J., dissenting). The constitutional interests of a patient in his or her final days are greater — and far more nuanced — than being free of pain. As such, the availability of pain-relief measures does not render the Ashcroft Directive any less of a threat to the constitutional rights of the individuals eligible for Oregon's DWDA.

* * * * *

While we believe that the individuals eligible for the DWDA have a liberty, privacy, and dignity right to physician-assisted suicide protected by the Fourteenth Amendment, this Court need not resolve that question today. Rather, under the doctrine of constitutional doubt, it is enough that such individuals have a serious claim to constitutional protection.

CONCLUSION

For the reasons stated, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

STEVEN R. SHAPIRO
The Americans Civil Liberties Union Foundation
125 Broad Street
New York, NY 10004

CHARLES F. HINKLE
ACLU Foundation of Oregon
Stoel Rives LLP
900 S.W. Fifth Avenue
Portland, OR 97204

ANDREW L. FREY
Counsel of Record
DAVID M. GOSSETT
KRISTINA SILJA BENNARD
Mayer, Brown, Rowe & Maw LLP
1909 K Street, N.W.
Washington, DC 20006
(202) 263-3000

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Supreme Court of the United States

ALBERTO R. GONZALES, in his official capacity as United States Attorney General, *et al.*,

Petitioners,

v.

State of OREGON, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Ninth Circuit

AMICI CURIAE BRIEF OF 52 RELIGIOUS AND RELIGIOUS FREEDOM ORGANIZATIONS AND LEADERS IN SUPPORT OF RESPONDENTS

GREGORY A. CASTANIAS
(*Counsel of Record*)
LAWRENCE D. ROSENBERG
EMILY M. MORRIS
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
(202) 879-3939
Counsel for Amici Curiae

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iv

INTEREST OF THE *AMICI* 1

STATEMENT 1

SUMMARY OF ARGUMENT 4

ARGUMENT 6

I. THE PEOPLE OF OREGON HAVE PROPERLY EXERCISED THEIR PREROGATIVE UNDER THE PRINCIPLES OF FEDERALISM TO ALLOW TERMINALLY ILL PATIENTS TO CHOOSE PHYSICIAN-ASSISTED DYING, UNDER HIGHLY CONTROLLED CIRCUMSTANCES, IN KEEPING WITH THEIR PERSONAL AND RELIGIOUS BELIEFS 6

A. The Decision to Seek a Physician's Assistance in Hastening One's Impending Death Is a Highly Personal and Religious Decision and Is Supported by a Substantial Body of Religious Thought and Doctrine 6

B. This Court Previously Ruled That the Decision Whether to Allow the Terminally Ill to Seek a Physician's Assistance in Hastening One's Impending Death Properly Belongs to the Individual States Under Principles of Federalism 12

C. The ODWDA Allows Oregon to Protect Individual Religious Freedom at a Level Its Citizens Deem Appropriate 15

TABLE OF CONTENTS
(continued)

Page

D. The Attorney General Has No Authority Simply to Adopt One Particular Social or Religious View and Override Oregon's Exercise of Its Federalism-Based Authority 18

1. Because Regulation of Medical Practices Is a Traditional State Power, a Federal Agency Can Regulate Medical Practices Only Under Clear Congressional Authorization 18

2. Neither the CSA Nor *Oakland Cannabis* Provides the Attorney General with the Authority Unilaterally to Impose His Own Social/Religious View to Override Oregon's Decision to Sanction Physician-Assisted Dying 20

3. Considerations of Federalism and Religious Freedom Point to Invalidating the Attorney General's Directive and Leaving Oregon's Law As Is 24

II. THOSE WHO SEEK TO OVERTURN THE ODWDA IGNORE THE INTERESTS IN HUMAN DIGNITY, INDIVIDUAL AUTONOMY, AND RELIGIOUS AND SPIRITUAL FREEDOM THAT IT REPRESENTS 26

A. There Is No Consensus Religious View Regarding the Morality and Religious Implications of Physician-Assisted Dying.....26

TABLE OF CONTENTS
(continued)

Page

B. The ODWDA Protects the Rights of the Terminally Ill and Affords All of Oregon's Citizens to Exercise Their Religious Freedom Consistent with Their Own Beliefs.....27

C. The States Should Be Allowed to Decide for Themselves How to Weigh Their Citizens' Religious and Other Interests Against Any Feared Problems from Physician-Assisted Dying ..29

CONCLUSION.....30

TABLE OF AUTHORITIES

Page

Cases

Addington v. Texas, 441 U.S. 418 (1979).....12
Atwater v. City of Lago Vista, 532 U.S. 318 (2001).....29
Barnhart v. Walton, 535 U.S. 212 (2002).....23
Barsky v. Bd. of Regents, 347 U.S. 442 (1954).....14, 18
Bates v. Dow Agrosciences LLC, 125 S. Ct. 1788 (2005).....24
Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984).....23
Christensen v. Harris County, 529 U.S. 576 (2000).....23
City of New York v. FCC, 486 U.S. 57 (1988).....21
Cooper v. California, 386 U.S. 58 (1967).....16
Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990).....7, 13, 18, 25, 26, 30
EEOC v. Wyoming, 460 U.S. 226 (1983).....14
Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council, 485 U.S. 568 (1988).....19-20
Gillette v. United States, 401 U.S. 437 (1971).....16-17
Gonzales v. Raich, 125 S. Ct. 2195 (2005).....21
Hillsborough County v. Automated Med. Labs., 471 U.S. 707 (1985).....18, 20
Linder v. United States, 268 U.S. 5 (1925).....18-19
Locke v. Davey, 540 U.S. 712 (2004).....17
La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355 (1986).....20-21
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).....18
New State Ice Co. v. Liebmann, 285 U.S. 262 (1932).....14
Oregon v. Ashcroft, 192 F. Supp. 2d 1077 (D. Or. 2002), *aff'd*, 368 F.3d 1118 (9th Cir. 2004).....4
Pegram v. Herdrich, 530 U.S. 211 (2000).....18, 21
PruneYard Shopping Ctr. v. Robins, 447 U.S. 74 (1980).....16

TABLE OF AUTHORITIES
(continued)

Page

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947).....19
San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1 (1973).....14
Skidmore v. Swift & Co., 323 U.S. 134 (1944).....23
Smith v. Robbins, 528 U.S. 259 (2000).....14
Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs, 531 U.S. 159 (2001).....19, 22
United States v. Lopez, 514 U.S. 549 (1995).....25
United States v. Mead Corp., 533 U.S. 218 (2001).....23
United States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483 (2001).....3, 22, 23
Vacco v. Quill, 521 U.S. 793 (1997).....1, 5
Walz v. Tax Comm'n of New York City, 397 U.S. 664 (1970).....17
Washington v. Glucksberg, 521 U.S. 702 (1997).....*passim*
Whalen v. Roe, 429 U.S. 589 (1977).....14, 19, 29
Will v. Mich. Dep't of State Police, 491 U.S. 58 (1989).....19
Zelman v. Simmons-Harris, 536 U.S. 639 (2002).....17

Statutes, Regulations, and Legislative Materials

21 U.S.C. § 801.....20
21 U.S.C. § 811(b).....24
21 C.F.R. § 1306.04.....19
Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Nov. 9, 2001).....3-5, 19, 22-25
Or. Rev. Stat. § 127.800.....2
Or. Rev. Stat. § 127.805.....2
Or. Rev. Stat. § 127.815.....2
Or. Rev. Stat. § 127.840.....3
Or. Rev. Stat. § 127.850.....3
Or. Rev. Stat. § 127.855.....3

TABLE OF AUTHORITIES
(continued)

Page

Or. Rev. Stat. § 127.880.....3
Or. Rev. Stat. § 127.890.....3
Lethal Drug Abuse Prevention Act of 1998, S. 2151, 105th Cong. (1998).....21
Pain Relief Promotion Act of 1999, H.R. 2260, 106th Cong. (2000) 21
Letter from Janet Reno, Attorney General, to Henry J. Hyde, Chairman, House Comm. on the Judiciary (June 5, 1998).....3, 20
California Compassionate Choices Act, A.B. 654, 2005-2006 Reg. Sess. (Cal. 2005).....25
Vermont Death with Dignity Act, H. 168, 2005-2006 Reg. Sess. (Vt. 2005) 25-26

Other Authorities

Belden Russonello & Stewart, *The View from Mainstream America: The Catholic Voter in 2004* (July 2004), *available at* http://www.dwd.org/documents/CFFC%202004.pdf.....11
Kathleen M. Boozang, *An Intimate Passing: Restoring the Role of Family and Religion in Dying*, 58 U. PITT. L. REV. 549 (1997) 6-7, 15, 28
Cynthia B. Cohen, *Christian Perspectives on Assisted Suicide and Euthanasia: The Anglican Tradition, in* PHYSICIAN ASSISTED SUICIDE: EXPANDING THE DEBATE (Margaret P. Battin *et al.* eds. 1998).....9
EPISCOPAL DIOCESE OF NEWARK, REPORT OF TASK FORCE ON ASSISTED SUICIDE (1996), *available at* http://www.dioceseofnewark.org/report.html.....8
Press Release, Field Research Corp., *By a Large Margin Californians Still Support the Concept of Doctor-Assisted Suicide* (Mar. 2, 2005), *available at* http://www.field.com/fieldpollonline/subscribers/RLS2155.pdf.....11

TABLE OF AUTHORITIES
(continued)

Page

Gary S. Gildin, *A Blessing in Disguise: Protecting Minority Faiths Through State Religious Freedom Non-Restoration Acts*, 23 HARV. J.L. & PUB. POL'Y 411 (2000).....17
GENERAL ASSEMBLY OF THE UNITARIAN UNIVERSALIST ASSOCIATION OF CONGREGATIONS, THE RIGHT TO DIE WITH DIGNITY (1988), *available at* http://www.uua.org/actions/health/88die-dignity.html 9
Press Release, Harris Interactive, *Survey Finds 2-to-1 Majorities Continue to Support Rights to Both Euthanasia and Doctor-Assisted Suicide* (Jan. 9, 2002), *available at* http://www.harrisinteractive.com/harris_poll/index.as?PID=278 11
GERALD LARUE, PLAYING GOD: FIFTY RELIGIONS' VIEWS ON YOUR RIGHT TO DIE (1996).....7
Penney Lewis, *Rights Discourse and Assisted Suicide*, 27 AM. J.L. & MED. 45 (2001) 16
Daniel C. Maguire, *Introduction: Charles E. Curran: Catholic Theologian, Priest, Prophet, in* A CALL TO FIDELITY: ON THE MORAL THEOLOGY OF CHARLES E. CURRAN (J. Walter *et al.* 2002).....11
REV. RALPH MERO, PAMPHLET, CHOICES IN DYING, *available at* http://www.uua.org/ pamphlet/3100.html....9
Rev. Robert K. Nace, *Assisted Suicide: Whose Choice Is It?* (Sept. 2000), *available at* http://www.ucc.org/ucnews/sep00/assist.htm.....8
Rev. Kenneth W. Phifer, A Hastened Death, Presentation at Final Exit Network Conference (Nov. 14, 2004), *available at* http://www.finalexitnetwork.org/hastened_death.htm.....30

TABLE OF AUTHORITIES
(continued)

Page

PRESBYTERIAN CHURCH (U.S.A.), CHRISTIAN FAITH AND LIFE AREA, CONGREGATIONAL MINISTRIES DIV., IN LIFE AND IN DEATH WE BELONG TO GOD: EUTHANASIA, ASSISTED SUICIDE, AND END-OF-LIFE ISSUES (1995) 10

Matthew P. Previn, Note, *Assisted Suicide and Religion: Conflicting Conceptions of the Sanctity of Human Life*, 84 GEO. L.J. 589 (1996).....7, 10, 15

Rev. John Shelby Spong, *Assisted Suicide: A Christian Choice and a New Freedom* (Feb. 12, 2003), *available at* http://www.beliefnet.com/story/121/story_12143_2.htm 8-9

Cristina L. Traina, *Pope & John Lecture on Professionalism: Religious Perspectives on Assisted Suicide*, 88 J. CRIM. L. & CRIMINOLOGY 1147 (1998)..... 11-12

Resolution: Rights and Responsibilities of Christians Regarding Human Death, *in* MINUTES OF THE UNITED CHURCH OF CHRIST SYNOD (1991) 8

UNITED METHODIST CHURCH, BOOK OF RESOLUTIONS (1992).....10

Melvin I. Urofsky, *Justifying Assisted Suicide: Comments on the Ongoing Debate*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 893 (2000).....7, 16, 28

Press Release, Yes on A.B. 654, *Diverse Group of Clergy Supports California Compassionate Choices Act* (May 26, 2005) 9-10, 12

Press Release, Zogby Int'l, *Vermonters Support Doctor-Assisted Suicide—Doctor-Aided Death Has 80% Vt. Support* (Jan. 6, 2005), *available at* http://www.dwd.org/documents/Zogby_Summary.doc 11

TABLE OF AUTHORITIES
(continued)

Page

Noam J. Zohar, *Deliberations on Suicide: Exceptions, Toleration, and Assistance*, *in* PHYSICIAN ASSISTED SUICIDE: EXPANDING THE DEBATE (Margaret P. Battin *et al.* eds. 1998).....10

INTEREST OF THE *AMICI*

This *amici curiae* brief is being filed on behalf of a diverse array of religious organizations, leaders, and scholars as well as advocates of religious liberty. *See* Appendix of *Amici Curiae*, attached. These organizations and leaders represent a variety of religious and spiritual faiths and their congregations that support an individual's freedom to choose physician-assisted dying as a moral and honorable means of ending one's life with dignity and grace. The *amici* therefore support Oregon's enactment of the Death With Dignity Act as a means of honoring and respecting each individual's freedom of religion and conscience in making this most deeply personal and sacred of choices.[1]

STATEMENT

1. Eight years ago in *Washington v. Glucksberg*, 521 U.S. 702 (1997), and *Vacco v. Quill*, 521 U.S. 793 (1997), this Court was asked to decide if, within the bounds of the Due Process Clause of the Fourteenth Amendment, a state has the power to decide whether or not to criminalize physician assistance to patients wishing to hasten their own impending deaths. This Court decided that the states do have such authority, emphasizing that the legitimacy of physician-assisted dying is far from a settled issue and that the national discussion and debate about how best to protect the dignity and independence of those who are terminally ill should continue. This Court therefore held that the individual states were free to make their own policy choices regarding this deeply personal, intimate, and important issue. *Glucksberg*, 521 U.S. at 735-36. As the Court concluded in *Glucksberg*, "[t]hroughout the Nation, Americans are engaged in an

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[1] Pursuant to Supreme Court Rule 37.6, no person other than counsel identified on the cover participated in authoring this brief. No entities other than *amici* and counsel provided financial support for this brief. Furthermore, the consent of the parties to the filing of this *amici curiae* brief has been obtained and filed with the Clerk of the Court.

earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." 521 U.S. at 735.

Concurring, Justice O'Connor explained:

> As the Court recognizes, States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. In such circumstances, "the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance."

Id. at 737 (O'Connor, J., concurring) (citations omitted).

2. On November 7, 1997, less than five months after the Court issued its decision in *Glucksberg*, the citizens of Oregon reaffirmed the Oregon Death with Dignity Act ("ODWDA" or "the Act") by decisively voting down a proposal to repeal the law. Originally enacted in 1994, the ODWDA establishes tightly controlled procedures under which competent, terminally ill adults under the care of an attending physician may obtain a prescription for Schedule II controlled substances in sufficient kind and quantity to allow them to control the time, place, and manner of their deaths. Or. Rev. Stat. § 127.805. The attending physician must determine, among other things, the patient's mental competence, Oregon residence, diagnosis, and prognosis, and the diagnosis and prognosis must be confirmed by a second physician. *Id.* §§ 127.800(8), 127.815. Only patients suffering from a "terminal illness," defined as "an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months," may be given such prescriptions. *Id.* § 127.800(12). The physician must then ensure that the patient understands his or her diagnosis and prognosis, the risks and probable results of taking the prescribed medication, and the alternatives to hastening his or her impending death, including, but not limited to, hospice care and pain relief. *Id.* § 127.800(7). Once a request from a

qualifying patient has been properly documented and witnessed, and all waiting periods have expired, the attending physician may prescribe, but not administer, medication that would enable the patient to end his or her life in a humane and dignified manner. *Id.* §§ 127.840, 127.850-.855, 127.880. The ODWDA immunizes physicians and pharmacists who act in compliance with its comprehensive procedures from civil or criminal sanctions, or professional disciplinary actions based on that conduct. *Id.* § 127.890.

3. In response to requests by members of Congress in late 1997, including then-Senator John Ashcroft, Attorney General Reno investigated the question of whether practitioners acting in accordance with the ODWDA could be subject to federal prosecution under the Controlled Substances Act ("CSA"). On June 5, 1998, Attorney General Reno issued a letter confirming that physician-assisted dying lies well outside the bounds of the CSA:

> The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA. . . . There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice.

Letter from Janet Reno, Attorney General of the United States, to Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998).

Three years later, however, Attorney General Ashcroft attempted to offset the CSA's silence on the issue by announcing his own policy, in the form of a "directive." *See* Pet. App. 100a, 104a. Relying in part on *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001), in which the Court found that no "medical necessity" exception was required by federal law or equity to the CSA's listing of marijuana as a substance with no currently confirmed medical benefits, Attorney General Ashcroft determined that

the CSA allows him to decide unilaterally that physician-assisted dying is not a "legitimate medical practice" under the CSA, thereby effectively overriding the ODWDA. Therefore, contrary to the position taken three years earlier by then-Attorney General Reno, the Ashcroft Directive threatens federal action against physicians and pharmacists acting under the ODWDA. *See* Pet. App. 100a-105a.

4. Upon the request of the State of Oregon, physicians and terminally ill patients, the U.S. District Court for the District of Oregon immediately entered a temporary restraining order against the Ashcroft Directive on November 8, 2001, and later permanently enjoined the Attorney General from giving any legal effect to the Ashcroft Directive, concluding that "Congress did not intend the CSA to override a state's decisions concerning what constitutes legitimate medical practice." *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1084 (D. Or. 2002). The Ninth Circuit agreed, holding that the Ashcroft Directive "violates the plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority." *Oregon v. Ashcroft*, 368 F.3d 1118, 1120 (9th Cir. 2004). The court of appeals thus continued the district court's injunction in full force and effect as its own. *Id.* at 1131. This Court has now granted certiorari to review the case.

SUMMARY OF ARGUMENT

Consistent with *Glucksberg* and the system of federalism outlined there, the ODWDA protects the spiritual interests of Oregon's terminally ill by allowing them, in certain limited situations, to control the timing and circumstances of their deaths. By unilaterally denying the legitimacy of physician-assisted dying as sanctioned by the people of Oregon, the Attorney General exceeded his statutory authority, and did nothing more than impose his unilateral moral and policy views on the people of Oregon.

The decision to choose physician-assisted dying is inevitably and deeply connected to an individual's personal

beliefs and concerns not only about bodily integrity, dignity, and autonomy, but also about the greater religious and spiritual implications of death and how one lives one's last moments. Accordingly, the decision to seek help in ending one's life is one that necessarily entails an individual's freedom of religion and conscience. Some faiths, religious organizations, and religious leaders steadfastly oppose physician-assisted dying, but that is by no means the universal view. Numerous faiths, religious organizations, and religious leaders strongly support physician-assisted dying as an entirely legitimate and moral choice by which the terminally ill can hasten their impending deaths with dignity and integrity.

For this and other reasons, this Court in *Washington v. Glucksberg* and *Vacco v. Quill* suggested that the heavily policy-laden choices regarding the morality and legality of physician-assisted dying should be left to the "laboratory" of the individual states. 521 U.S. at 737 (O'Connor, J., concurring). The states should be permitted not only to experiment with various approaches to the issue but also to honor the varying religious and spiritual views of their citizens. In this way, Oregon has chosen to allow its citizens the freedom of personal and religious choice in deciding for each of themselves whether physician-assisted dying fits with their religious and spiritual beliefs.

Attorney General Ashcroft's Directive, which prohibits the use of controlled substances for these purposes, tramples not only on state sovereign authority but also on the greater freedom of religion and conscience that Oregon has chosen to grant its citizens. The Ashcroft Directive thus exceeds the Attorney General's authority under the CSA. The CSA does not grant the Attorney General the power to usurp traditional state powers to regulate medical practice or standards, and it certainly does not give the Attorney General power to encroach upon state religious freedom. Rather, the CSA addresses only the need to regulate controlled substances across state lines to protect against drug abuse.

At its core, this case is about social policy, religious freedom, and preserving the right to pursue one's individual beliefs about human dignity, personal autonomy, and spirituality. The heart of this case is the right of the states and their citizens to decide for themselves the weighty and intensely personal and spiritual question of whether to allow terminally ill patients to seek the aid of their physicians in dying as a means to relieve their pain and suffering and preserve their dignity in accordance with their own beliefs.

ARGUMENT

I. THE PEOPLE OF OREGON HAVE PROPERLY EXERCISED THEIR PREROGATIVE UNDER THE PRINCIPLES OF FEDERALISM TO ALLOW TERMINALLY ILL PATIENTS TO CHOOSE PHYSICIAN-ASSISTED DYING, UNDER HIGHLY CONTROLLED CIRCUMSTANCES, IN KEEPING WITH THEIR PERSONAL AND RELIGIOUS BELIEFS

A. The Decision to Seek a Physician's Assistance in Hastening One's Impending Death Is a Highly Personal and Religious Decision and Is Supported by a Substantial Body of Religious Thought and Doctrine

While it is true that some people believe that physician-assisted dying is immoral, sinful, or even dangerous, for many others, physician-assisted dying instead offers a necessary means to ending unnecessary suffering and to preserving human dignity and independence in a way that is neither immoral nor sinful, but is in keeping with the exercise of one's own beliefs and conscience. For the terminally ill, choosing how to confront death is an intensely personal decision. Anxieties over the loss of dignity and autonomy are integrally bound up with concerns about ensuring that the conditions of one's death reflect one's own deeply held religious and spiritual beliefs:

> Religion continues to be inextricably linked with death for many patients and families. Death compels us to confront the meaning of existence, mortality, and the possibility of a hereafter. Religion provides to some both answers and methods for resolving these issues. . . . Religiously-based ethical systems often provide normative guidance or even specific directives to resolve the dilemmas posed by the treatment choices of a dying or very ill patient.

Kathleen M. Boozang, *An Intimate Passing: Restoring the Role of Family and Religion in Dying*, 58 U. PITT. L. REV. 549, 560-61 (1997) (footnote omitted). For these reasons, this Court has emphasized that any question concerning "the right to die," such as that presented here, "is a perplexing question with unusually strong moral and ethical overtones." *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 277 (1990).

The issues surrounding physician-assisted dying thus implicate a wide diversity of religious and spiritual liberty beliefs. There is no monolithic religious view in this country on the question of physician-assisted dying. *See, e.g.*, Melvin I. Urofsky, *Justifying Assisted Suicide: Comments on the Ongoing Debate*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 893, 913 (2000); GERALD A. LARUE, PLAYING GOD: FIFTY RELIGIONS' VIEWS ON YOUR RIGHT TO DIE 8 (1996); Matthew P. Previn, Note, *Assisted Suicide and Religion: Conflicting Conceptions of the Sanctity of Human Life*, 84 GEO. L.J. 589, 596-601 (1996). "[I]ndividuals of different religious faiths make different judgments and choices about whether to live on under such circumstances." *Glucksberg*, 521 U.S. at 746 (Stevens, J., concurring). Terminally ill patients' interests in religious and spiritual freedom thus dictate that they be allowed to make this choice according to their own beliefs, unfettered by the religious beliefs of others. As Justice Stevens noted in *Glucksberg*, "[a]voiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly [a]t the heart of [the] liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." 521 U.S. at 745 (Stevens, J., concurring) (citation and internal quotation marks omitted).

Religious organizations and religious leaders have taken a wide variety of positions on the morality of physician-assisted dying, and some religious denominations have even expressly endorsed an individual's moral prerogative to choose assisted dying. For example, the United Church of Christ General Synod passed a resolution in 1991 entitled, "Rights and Responsibilities of Christians Regarding Human Death," in which the Church affirmed the right to choose how one's life should end. MINUTES OF THE UNITED CHURCH OF CHRIST SYNOD at 18 (1991); *see also* Reverend Robert K. Nace, Assisted Suicide: Whose Choice Is It? (Sept. 2000), http://www.ucc.org/ucnews/sep00/assist.htm ("We are created by God and our life is not ours to squander, to take away or wish away or to hang on too tightly. To hang onto too tightly is the idolatry of our life, a pervasive sin of our culture enhanced by the skill of modern medicine.").

Similarly, the Episcopal Diocese of Newark's Task Force on Assisted Suicide concluded that in many circumstances, physician-assisted dying "can be theologically and ethically justified" when a terminally ill person makes a voluntary and informed choice after all reasonable means of ameliorating his or her suffering have been exhausted. EPISCOPAL DIOCESE OF NEWARK, REPORT OF TASK FORCE ON ASSISTED SUICIDE, 9 (1996), *available at* http//www.dioceseofnewark.org/report.html. Indeed, the now-retired Bishop John Shelby Spong of the Episcopal Diocese of Newark strongly supports the rights of the terminally ill to choose physician-assisted dying:

> [T]he values marking the Christian faith and those motivating the "Death with Dignity" movement begin to merge. The key to this union lies in the commitment by both groups to defend the dignity and sacredness of human life. . . . Do we not serve our deepest convictions if we decide to end our life at the moment in which its sacredness becomes compromised? . . . As such we must also be responsible with God for guaranteeing the goodness of our deaths.

The Right Reverend John Shelby Spong, *Assisted Suicide: A Christian Choice and a New Freedom* (Feb. 12, 2003), *available at* http://www.beliefnet.com/story/121/story_12143_2.htm. Some in the Anglican Church have also adopted a similar stance. *See* Cynthia B. Cohen, *Christian Perspectives on Assisted Suicide and Euthanasia: The Anglican Tradition, in* PHYSICIAN ASSISTED SUICIDE: EXPANDING THE DEBATE 335, 338 (Margaret P. Battin *et al.* eds. 1998) (noting that many believe that prolonged physical pain, depersonalization, loss of control, and bodily deterioration "serv[e] no discernible spiritual or other purpose" and "can be destructive of moral and spiritual values").

In 1988, the Unitarian Universalist Association became the first large denomination in North America to take an explicit stand in support of the right to die with dignity through assisted dying. The General Assembly of the Unitarian Universalist Association supports "the right to self-determination in dying, and the release from civil or criminal penalties of those who, under proper safeguards, act to honor the right of terminally ill patients to select the time of their own deaths." GENERAL ASSEMBLY OF THE UNITARIAN UNIVERSALIST ASSOCIATION OF CONGREGATIONS, THE RIGHT TO DIE WITH DIGNITY (1988), *available at* http://www.uua.org/actions/health/88die-dignity.html; *see also* REV. RALPH MERO, PAMPHLET, CHOICES IN DYING, *available at* http://www.uua.org/ pamphlet/3100.html (last visited 7/15/05) ("[M]any Unitarian Universalists accept assisted suicide as an option for terminally ill patients or others struggling in conditions of irreversible suffering and hopeless deterioration.").

Various branches of Judaism also teach sympathy, understanding, and respect for those who choose assistance in hastening death, and some Jewish organizations take the position that a competent, terminally ill adult has the right to hasten death voluntarily with the aid of a physician. *See, e.g.*, Press Release, Yes on AB 654, Diverse Group of Clergy Supports California Compassionate Choices Act (May 26,

2005) ("What is most important is for people to know they have a choice, and to enable them to make the best end-of-life decisions for themselves.") (quoting Rabbi Joshua Stampfer); Noam J. Zohar, *Jewish Deliberations on Suicide: Exceptions, Toleration, and Assistance*, *in* Battin *et al.* 362, 368 (explaining that some Jewish teachings allow "any person finding himself in dire strai[t]s . . . to seek escape through suicide").

In addition, a variety of Protestant denominations that have not adopted any formal position on physician-assisted dying do encourage compassion, sympathy, and support for those who choose this option. For example, the Presbyterian Church has endorsed the view that "basic Christian respect for persons demands that a person's decisions about death be honored in most instances." PRESBYTERIAN CHURCH (U.S.A.), CHRISTIAN FAITH AND LIFE AREA, CONGREGATIONAL MINISTRIES DIVISION, IN LIFE AND IN DEATH WE BELONG TO GOD: EUTHANASIA, ASSISTED SUICIDE, AND END-OF-LIFE ISSUES 47 (1995) (citing 195th General Assembly position on "The Covenant of Life and the Caring Community" (1983)); *see also* Press Release, Yes on AB 654, *supra* ("When we live as though death is the worst thing that can happen to us, we lose the zest for living. The [California] Compassionate Choices Act allows one to have a 'good death'.") (quoting Rev. Paul Smith of the First Presbyterian Church of Brooklyn, New York). The United Methodist Church has adopted a similar approach. *See* UNITED METHODIST CHURCH, BOOK OF RESOLUTIONS 144 (1992).

Yet other traditions of religious thought and freedom of conscience also affirmatively support an individual's right to seek physician-assisted dying. "Both Buddhism and Shintoism permit suicide when an individual with an incurable disease is in pain." Previn, Note, *supra*, at 597 (footnotes omitted). Likewise, the humanist tradition endorses the ethical viewpoint that because every individual has the right to live with dignity, every individual has the right to die with dignity, and physician-assisted dying is

therefore a legitimate moral choice in certain circumstances. *Id.* at 599.

In keeping with this support for physician-assisted dying, polls demonstrate that the vast majority of Americans of all faiths support physician-assisted dying. A national 2001 poll revealed that a majority of 61% to 34% of adults would favor enacting a law like Oregon's in their states, and 58% versus 35% believed that Attorney General Ashcroft was wrong to try to overrule the ODWDA. Press Release, Harris Interactive Survey (Jan. 9, 2002). By a majority of 65% to 29%, those surveyed also thought that "the law should allow doctors to comply with the wishes of a dying patient in severe distress who asks to have his or her life ended." *Id.* And with regard to individual states:

- In California, 65% of Catholics, 63% of Protestants and other Christians, and 83% of those of other faiths believe that incurably ill patients should have the right to ask for and receive life-ending medication. Press Release, Field Research Corp. (Mar. 2, 2005);
- 72% of Vermont adults believe that the decision about whether they should be able to bring a peaceful end to their own suffering should be theirs and "not God's." Press Release, Zogby Int'l (Jan.6, 2005).

Indeed, even within religions that institutionally oppose physician-assisted dying, many individual members hold a different view consistent with their own religious beliefs. *See, e.g.*, Belden Russonello & Stewart, *The View from Mainstream America: The Catholic Voter in Summer 2004* at 58 (July 2004) (showing that 53% of Catholic voters support physician assistance in dying); Daniel C. Maguire, *Introduction: Charles C. Curran: Catholic Theologian, Priest, Prophet*, *in* A CALL TO FIDELITY: ON THE MORAL THEOLOGY OF CHARLES E. CURRAN 8 (J. Walter *et al.* 2002) ("There is 'a legitimacy of ethical pluralism within Catholic moral theology' on the subject of assisted suicide. 'Catholic theology' is not simply Vatican theology, since Catholic theology is broader and more nuanced.") (citations omitted); Cristina L.H. Traina, *Pope & John Lecture on*

Professionalism: Religious Perspectives on Assisted Suicide, 88 J. CRIM. L. & CRIMINOLOGY 1147, 1151 (1998) ("Even within those religious bodies in which concord or autocratic authority is strong enough to generate a position, there are conscientious people who dissent."). In fact, over a hundred clergy from nine denominations and faith communities support California's Compassionate Choices Act, which is similar to the ODWDA. Press Release, Yes on AB 654, *supra*.

This vast array of views on assisted dying demonstrates its significant support within and throughout the religious community. The ODWDA thus protects Oregon citizens' freedom to exercise their own religious and spiritual beliefs by allowing them to decide for themselves whether physician-assisted dying comports with those beliefs.

B. This Court Previously Ruled That the Decision Whether to Allow the Terminally Ill to Seek a Physician's Assistance in Hastening One's Impending Death Properly Belongs to the Individual States Under Principles of Federalism

As this Court held in *Glucksberg*, the issues surrounding physician-assisted dying implicate a number of state interests. *Glucksberg*, 521 U.S. at 728-35. It is therefore up to the states to decide how to weigh those various and sometimes conflicting interests—and, in turn, how to treat the ultimate issue of physician-assisted dying as a matter of state law. *Id.* at 735. Certainly, one of those state interests lies in "protecting the integrity and ethics of the medical profession." *Id.* at 731. Another is an interest in "the preservation of human life" and in protecting vulnerable groups such as the poor, the elderly, the disabled, and the terminally ill. *Id.* at 728, 731-32; *see also Addington v. Texas*, 441 U.S. 418, 426 (1979) (noting that a state "has a legitimate interest under its *parens patriae* powers" to decide how best to provide for its more vulnerable citizens). And the states also have an undeniable interest in protecting an individual's "liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of

human life" according to his or her own religious beliefs. *Glucksberg*, 521 U.S. at 745 (Stevens, J., concurring) (citation and internal quotation marks omitted).

None of these interests is absolute. Rather, state citizens and state legislatures have the discretion and duty to balance these interests. In a federal system, different states will strike the balance differently. Indeed, in *Cruzan*, this Court emphasized that it is up to the states to make policy-based decisions regarding their citizens' rights to die: "The choice between life and death is a deeply personal decision of obvious and overwhelming finality. We believe [the States] may legitimately seek to safeguard the personal element of this choice . . . ." 497 U.S. at 281. Thus, "a State may properly decline to make judgments about the 'quality' of life that a particular individual may enjoy," and instead weigh its interest in the preservation of human life against the "the constitutionally protected interests of the individual." *Id.* at 282; *see also id.* at 293 n.1 (Scalia, J., concurring) (emphasizing that with regard to the right to die, "it is up to the citizens of [the States] to decide, through their elected representatives, whether that wish will be honored"). This is particularly true with regard to questions such as the right to die, which "is a perplexing question with unusually strong moral and ethical overtones." *Id.* at 277.

The Court in *Glucksberg* therefore quite pointedly refused to "place the matter outside the arena of public debate and *legislative* action," lest it simply become "transformed into the policy preferences" of a few individuals. 521 U.S. at 720 (emphasis added). Instead, the Court expressed its hope that the debate over physician-assisted dying would continue in the states. "Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735.

Accordingly, with regard to physician-assisted dying, "'the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the

"laboratory" of the States . . . in the first instance.'" *Id.* at 737 (O'Connor, J., concurring). This Court has long recognized that the role of the states in acting as laboratories of social and economic innovation constitutes a critical component of our federalist system. As Justice Brandeis wrote in his oft-quoted dissent in *New State Ice Co. v. Liebmann*, "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting); *accord EEOC v. Wyoming*, 460 U.S. 226, 265 (1983) (Burger, C.J., dissenting). The virtues of state experimentation are particularly evident in areas involving "problems of vital local concern," such as medical care and regulation of the medical profession. *Whalen v. Roe*, 429 U.S. 589, 597 (1977). State experimentation is also of particular value on "difficult questions of policy," *Smith v. Robbins*, 528 U.S. 259, 272 (2000); *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 50 (1973), such as physician-assisted dying, which concerns not only an individual's fundamental interests in human dignity and relief from pain and suffering but also a wide diversity of religious and spiritual liberty interests as well, *Glucksberg*, 521 U.S. at 746-47 (Stevens, J., concurring).

The "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide" is therefore precisely the kind of difficult policy question that is best left to state experimentation and therefore reserved to the states in this Court's decision in *Glucksberg*. *Id.* at 735. As the Court explained in *Glucksberg*, the states are especially well-suited to advancing the debate over physician-assisted dying. They "have superior opportunities to obtain the facts necessary for a judgment about [physician-assisted dying]." *Id.* at 788 (Souter, J., concurring); *see also Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) (noting that the states have much greater experience in supervising medical practice and establishing

detailed procedures for doing so). In addition, they have "the power to experiment, moving forward and pulling back as facts emerge within their own jurisdictions." *Glucksberg*, 521 U.S. at 788 (Souter, J., concurring). Indeed, "experimentation . . . is entirely proper, as well as highly desirable" in the ongoing debate over physician-assisted dying. *Id.* at 789 (Souter, J., concurring).

C. The ODWDA Allows Oregon to Protect Individual Religious Freedom at a Level Its Citizens Deem Appropriate

Physician-assisted dying necessarily entails the states' sovereign power to protect not only their citizens' substantial liberty interests in dignity, independence, and relief from suffering, but also their citizens' substantial religious liberty interests in keeping this decision free from governmental interference. Accordingly, consistent with the Court's suggestions in *Glucksberg*, the people of Oregon have carried forward the debate over physician-assisted dying. Oregonians engaged in exactly the kind of "extensive and serious evaluation of physician-assisted suicide" suggested in *Glucksberg*, *id.* at 737 (O'Connor, J., concurring), and for a second time approved the ODWDA as a legitimate means to protect the personhood, dignity, and spiritual interests and autonomy of terminally ill patients in Oregon by enabling them to relieve their own suffering and leave life in the way that best comports with their beliefs.

Much of the debate surrounding physician-assisted dying concerns the various religious and moral views about "the sanctity of life" and how best to protect it. *See, e.g.*, Boozang, *supra*, at 565-98; Previn, Note, *supra*. As this Court acknowledged in *Glucksberg*, one of the bases for the Anglo-American tradition of prohibiting suicide is the idea that "'[suicide] is an Offence against Nature, against God, and . . . is contrary to Nature and a Thing most horrible.'" 521 U.S. at 712 n.10. Indeed, the inherently and deeply religious and spiritual nature of the issue can already be seen from looking at the identities of the various *amici* who have filed in support of the petitioner. *See, e.g.*, Br. of Focus on

the Family & the Family Research Council; Br. of the U.S. Conf. of Catholic Bishops *et al.*; Br. of the Christian Med. Ass'n *et al.*; Br. of the Catholic Med. Ass'n.

The freedom to choose physician-assisted dying, then, constitutes in large part a freedom of religious choice—specifically, freedom from the imposition of others' religious beliefs in a way that restricts one's fundamental and deeply personal choices about how the last moments of one's life should be lived. *See* Penney Lewis, *Rights Discourse and Assisted Suicide*, 27 AM. J.L. & MED. 45, 60 (2001) ("[F]or the state to interfere in the moral decision of an individual to take her life violates her right to freedom of conscience."); Urofsky, *supra*, at 942 ("[T]here is no justifiable reason why one religion or one group or one individual should be able to impose their views on others."); Bishop Spong, *supra* ("[T]he basic human right to choose how and when to die should be guaranteed by law and respected by our communities of faith."). Thus, by protecting the interests of Oregonians in relief from suffering and death in a manner that best comports with their beliefs, the ODWDA represents a state's choice to protect individual exercise of freedom of religion and conscience. Oregon's authority to promulgate such a measure should therefore be respected.

Indeed, it is a basic principle of "Our Federalism" that, regardless of the exact contours of an individual's rights under the Establishment and Free Exercise Clauses (or the other parts of the federal Constitution), the states are allowed to provide their citizens with even greater protections than those afforded under the federal Constitution. *See PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 81 (1980) (noting that a state may "exercise its police power or its sovereign right to adopt in its own Constitution individual liberties more expansive than those conferred by the Federal Constitution"); *Cooper v. California*, 386 U.S. 58, 62 (1967) (similar); *see also Gillette v. United States*, 401 U.S. 437, 453 (1971) ("Quite apart from the question whether the Free Exercise Clause might require some sort of exemption, it is hardly impermissible for Congress to attempt to

accommodate free exercise values . . . .") (footnote omitted). In fact, the Court's decision in *Glucksberg* on this very issue strongly suggests that, even if a fundamental liberty interest in physician-assisted dying does not exist under the Fourteenth Amendment of the federal Constitution, such a right could very well exist under a state constitution or be granted by state law. 521 U.S. at 735; *see also* Gary S. Gildin, *A Blessing in Disguise: Protecting Minority Faiths Through State Religious Freedom Non-Restoration Acts*, 23 HARV. J.L. & PUB. POL'Y 411, 436 (2000) (interpreting *Glucksberg* to mean that "the judgment to maximize the free exercise of religion is entirely consistent with the constitutional scheme that empowers each state to resolve the debate over affording rights, above the threshold fixed by the Constitution, as the majority sees fit").

Such state prerogatives to grant enhanced religious freedoms also spring in part from the role of the states as "experimental laboratories" under the principles of federalism. "'States, while bound to observe strict neutrality, should be freer to experiment with involvement [in religion]—on a neutral basis—than the Federal Government'" and in this way "strike a proper balance" between the demands of the Constitution "on the one hand and the federalism prerogatives of States on the other." *Zelman v. Simmons-Harris*, 536 U.S. 639, 678-79 (2002) (Thomas, J., concurring) (quoting *Walz v. Tax Comm'n of City of New York*, 397 U.S. 664, 699 (1970) (Harlan, J., concurring)) (footnote omitted). The states are thus free to draw "a more stringent line" as to what they consider necessary for freedom of religion than does the federal Constitution. *See Locke v. Davey*, 540 U.S. 712, 721-22 (2004).

The ODWDA permits terminally ill Oregonians to depart life in a way that best comports with their spiritual beliefs. Those individuals who believe that physician-assisted dying is a moral and spiritually legitimate or even required choice may do so according to the dictates of their consciences and their beliefs. Those who believe that physician-assisted

dying is not a moral or ethical choice also have the freedom to follow their own consciences and beliefs by not choosing this option. In this way, Oregon has elected to protect the religious freedoms and spiritual interests of all of its citizens. As Justice Stevens remarked in *Cruzan*, "not much may be said with confidence about death unless it is said from faith, and that alone is reason enough to protect the freedom to conform choices about death to individual conscience." 497 U.S. at 343 (Stevens, J., dissenting). By stepping in and making the unilateral decision to override Oregon's sovereign choice in the matter, the Attorney General plainly interfered with Oregon's authority to experiment with the difficult moral, religious, and other policy questions implicated by physician-assisted dying.

D. The Attorney General Has No Authority Simply to Adopt One Particular Social or Religious View and Override Oregon's Exercise of Its Federalism-Based Authority

1. Because Regulation of Medical Practices Is a Traditional State Power, a Federal Agency Can Regulate Medical Practices Only Under Clear Congressional Authorization

Regulation of the practice of medicine, and in particular, regulation of the standards of reasonable medical care, is a traditional state power. "[T]he field of health care [is] a subject of traditional state regulation." *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000); *accord Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985). "It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power [and] extends naturally to the regulation of all professions concerned with health." *Barsky*, 347 U.S. at 449. Indeed, eighty years ago the Court called it "[o]bvious[]" that "direct control of medical practice in the states is beyond the power of the Federal Government."

Linder v. United States, 268 U.S. 5, 18 (1925). More recently, the Court has stated that it is "well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen*, 429 U.S. at 603 n.30.

In this case, the Attorney General claims that the CSA grants him the authority to regulate what qualifies as a "legitimate medical purpose" in each state and has declared that physician-assisted dying is not a "legitimate medical purpose" anywhere (but with specific reference to Oregon) for substances controlled under the CSA. *See* Pet. App. 102a (interpreting 21 C.F.R. § 1306.04(a)). Because regulating standards of reasonable medical care is a traditional state power, however, the Attorney General must identify a "clear and manifest" statement of congressional intent to grant him such authority under the CSA. *See Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

As this Court has repeatedly made clear with regard to federal agency incursion into traditional state powers such as the practice of medicine:

> Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. This requirement stems from our prudential desire not to needlessly reach constitutional issues and our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority. This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power. Thus, "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."

Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs, 531 U.S. 159, 172-73 (2001) (citing *Edward J.*

DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council, 485 U.S. 568, 575 (1988)); *accord Automated Med. Labs.*, 471 U.S. at 715-16. As demonstrated below, the Attorney General has no such authority.

2. Neither the CSA Nor *Oakland Cannabis* Provides the Attorney General with the Authority Unilaterally to Impose His Own Social/Religious View to Override Oregon's Decision To Sanction Physician-Assisted Dying

The CSA does not give the Attorney General the authority to impose his social policy agenda on states such as Oregon that have, through the democratic process, chosen to protect the spiritual and autonomy interests of the terminally ill. The CSA does not address standards of medical care or accepted medical procedures, much less the social or religious ramifications of physician-assisted dying; it instead speaks only to the safe classification and distribution of controlled substances as part of interstate commerce to protect against drug abuse and "quack" medicines. *See* 21 U.S.C. § 801; *see also* Reno Letter, *supra*. Neither the plain language nor the purpose of the CSA invests the Attorney General with such sweeping authority to override Oregon's considered policy choice under the guise of regulating "legitimate medical purposes."

A federal agency's authority to override traditional state authority is dependent on Congress' intent:

> First, an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it. Second, the best way of determining whether Congress intended the regulations of an administrative agency to displace state law is to examine the nature and scope of the authority granted by Congress to the agency. . . . An agency may not confer power upon itself. To permit an agency to expand its power in the face of a congressional limitation on its jurisdiction would be to grant to the agency power to override Congress. This we are both unwilling and unable to do.

La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374-75 (1986); *accord City of New York v. FCC*, 486 U.S. 57, 64 (1988).

As this Court noted in its recent decision in *Gonzales v. Raich*, "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." 125 S. Ct. 2195, 2203 (2005). Drugs are therefore scheduled according to their high potential for abuse, lack of any accepted medical use, and absence of safety for use in medically supervised treatment. *Id.* at 2203-04. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping. *Id.* at 2204. The CSA does not, however, give the Attorney General the authority to regulate the practice of medicine, an area traditionally reserved to the states. *See Pegram*, 530 U.S. at 237. The CSA says nothing about standards of care, licensing, medical ethics, accepted medical procedures, and the like. Indeed, given the states' elaborate regimes that regulate the practice of medicine, *see, e.g., id.* at 237, it would be extremely odd for Congress to have intended to silently displace such state regulation.

The CSA is thus a law enforcement statute, not a medical policy act.[2] Accordingly, the CSA should not, under principles of both federalism and federal deference to state

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[2] Indeed, if the 105th and 106th Congresses had believed that the CSA reaches the use of controlled substances in physician-assisted dying, they would not have introduced the Lethal Drug Abuse Prevention Act of 1998, *see* S. 2151, 105th Cong. (1998), or the Pain Relief Promotion Act of 1999, *see* H.R. 2260, 106th Cong. (2000), both of which, had they passed, would have specifically expanded the scope of the CSA to nullify the ODWDA. It is thus apparent that, after this Court's decision in *Glucksberg*, at least some members of Congress viewed the CSA as not speaking to the use of controlled substances in physician-assisted dying.

power, be construed to allow the Attorney General to make pronouncements based on unilateral judgments about the social value of various medical practices using perfectly legal drugs of known medical efficacy. This Court should thus "read the statute as written to avoid the significant constitutional and federalism questions raised by respondents' interpretation, and therefore reject the request for administrative deference." *Solid Waste Agency of N. Cook County*, 531 U.S. at 174 .

For these same reasons, it is plain that this Court's decision in *Oakland Cannabis* did not hold that the CSA gives the Attorney General authority to define what constitutes a "legitimate medical purpose." *See* 532 U.S. at 493. In *Oakland Cannabis*, the first challenge to California's legalization of medical marijuana use, the Court rejected the argument that federal law required a "medical necessity" exception to the CSA's ban on marijuana, finding that the CSA precludes such an exception. *Id.* at 493-95. Extrapolating from the Court's decision in *Oakland Cannabis*, the Department of Justice's Office of Legal Counsel ("OLC") reasoned that, like California's medical marijuana law, the ODWDA must also be an attempt to "abrogate" or "supersede" the CSA. Pet. App. 131a, 133a-134a. In a June 2001 opinion written at the Attorney General's request, the OLC therefore characterized Oregon as attempting "by its unilateral action, [to] take its physicians' conduct out of the scope of otherwise nationally applicable prohibitions on the dispensing of controlled substances." Pet. App. 134a.

Oakland Cannabis, however, is inapposite to this case. For one thing, the California statute at issue in *Oakland Cannabis* is entirely different from the ODWDA. In no way does the ODWDA attempt to "abrogate" or "supersede" federal law. Oregon has not sought to legalize what the CSA has expressly banned or to challenge the CSA's classification scheme—how could it, when the CSA says nothing about physician-assisted dying or the use of controlled substances for this purpose? Rather, Oregon has

simply legalized a medical practice that uses drugs already fully authorized for medical use under the CSA. For another thing, *Glucksberg* preserves the individual states power to regulate through the political process the issue of whether physician-assisted dying is a "legitimate medical purpose." 521 U.S. at 735. Indeed, the ODWDA is likely the kind of duly enacted state statute, well within Oregon's sovereign power and well outside the CSA, that Justice Stevens anticipated when he stated, in *Oakland Cannabis*, that the federal government must "show[ ] respect for the sovereign States that comprise our Federal Union. That respect imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country." 532 at 502 (Stevens, J., concurring) (quotation marks omitted).

For these reasons, as an agency interpretation of federal law the Ashcroft Directive merits neither *Chevron* nor *Skidmore* deference. Under *Chevron*, a court should defer to agency interpretations of a statute only if the agency was granted authority to render such interpretations—and even then, often only if the agency has expertise in the area and has been consistent in its interpretation, among other considerations. *See Barnhart v. Walton*, 535 U.S. 212, 222 (2002) (discussing *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)); *United States v. Mead Corp.*, 533 U.S. 218, 231-34 (2001) (same). And in all events, *Chevron* deference does not apply to informal interpretive rulings, such as the Ashcroft Directive. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000).

Similarly, the lesser deference accorded under *Skidmore* depends upon, among other things, the validity, persuasiveness and consistency of the agency's interpretation of its authority. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). As a purported agency interpretation of the CSA, the Ashcroft Directive obviously fails under both *Chevron* and *Skidmore*.

First, the CSA in no way provides any "clear statement" that the Attorney General has the authority to ban all use of controlled substances in physician-assisted dying—indeed, the CSA does not speak to standards of medical care at all, much less speak to such value-laden issues of public policy as assisted dying.

Second, the Attorney General has no expertise in the areas of medical practice, standards medical of care, social policy with respect to medical care, much less expertise on the individual spiritual choices of terminally ill patients. *See* 21 U.S.C. § 811(b) (denying the Attorney General the power to make medical or scientific decisions with regard to drug control).

Third, under the previous administration, Attorney General Reno made plain that the CSA does not in any way speak to the OWDWA. *See Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1801 (2005) (finding agency's claim of pre-emptive authority under statute "particularly dubious" where five years earlier the government had repudiated such an interpretation of the statute).

Finally, as noted by the Patient-Respondents (Br. at 15-19), neither Attorney General Ashcroft nor the OLC considered the substantial body of information, including comprehensive annual reports, about the actual practices of physicians and experiences of patients under the procedures enacted in the ODWDA.

3. Considerations of Federalism and Religious Freedom Point to Invalidating the Attorney General's Directive and Leaving Oregon's Law As Is

The Ashcroft Directive impermissibly burdens Oregon's efforts to create a regime of personal and religious choice and freedom and instead simply imposes on the entire polity only one select set of religious and personal beliefs about the issue. By establishing an absolute proscription on physician-assisted dying via the use of controlled substances, the Attorney General has thus prematurely ended democratic

debate among the states and the people on this issue in a way that was never authorized under the CSA. *See Glucksberg*, 521 U.S. at 735 (refusing "to place the matter [of assisted suicide] outside the arena of public debate and *legislative* action," lest it simply become "transformed into the policy preferences" of a few individuals) (emphasis added).

The people of Oregon have sought to enhance religious freedoms, rather than restrict them, while the Attorney General has sought impermissibly to burden Oregon's right to do so under the principles of federalism. Oregon was acting within its sovereign authority in not only regulating medical practices and standards within the states but also in further protecting religious freedoms. "We do not see any reason why important individual interests should be afforded less protection simply because the government finds itself in the position of defending them." *Cruzan*, 497 U.S. at 282 n.10. Moreover, the ODWDA is entirely consistent with this Court's holding that policy choices regarding physician-assisted dying should be an issue commended to the discretion of the individual states as "laborator[ies]." 521 U.S. at 737 (O'Connor, J., concurring). The ODWDA thus not only allows federalism to flourish but also protects individual religious freedom.

All of these factors strongly militate against any idea that Congress meant the CSA to trump the states' sovereign authority in this regard. The Court has been particularly protective of state sovereignty when federal law prevents "the States from experimenting and exercising their own judgment in an area to which States lay claim by right of history and expertise." *United States v. Lopez*, 514 U.S. 549, 583 (1995) (Kennedy, J., concurring). Thus, the ODWDA is a legitimate exercise of the authority reserved to Oregon under the principles of federalism by this Court in *Glucksberg*. And although the voter initiative in Oregon is the only one that has been successful thus far, at least twenty-five similar proposals have been made in twenty other states. *See, e.g.*, A.B. 654, 2005-2006 Reg. Sess. (Cal. 2005) ("California Compassionate Choices Act"); H. 168,

2005-2006 Reg. Sess. (Vt. 2005) ("Vermont Death With Dignity Act").

Indeed, because religious and personal beliefs about physician-assisted dying are hardly monolithic, there is, at this point, no basis on which the Attorney General could have set forth a national policy on this issue. To have done so was thus tantamount to allowing the Attorney General to set moral and religious policy for the entire country. "[I]n deciding 'a question of such magnitude and importance . . . it is the [better] part of wisdom not to attempt, by any general statement, to cover every possible phase of the subject." *Cruzan*, 497 U.S. at 277-78. Rather, as Justice Scalia emphasized in *Cruzan*, with regard to the right to die, "it is up to the citizens of [the States] to decide, through their elected representatives, whether that wish will be honored." *Id.* at 293 (Scalia, J., concurring). The Attorney General's attempt single-handedly to overrule Oregon's decision thus impermissibly interferes with not only Oregon's authority under principles of federalism but also the religious and personal freedom that Oregon has granted its citizens under that authority.

II. THOSE WHO SEEK TO OVERTURN THE ODWDA IGNORE THE INTERESTS IN HUMAN DIGNITY, INDIVIDUAL AUTONOMY, AND RELIGIOUS AND SPIRITUAL FREEDOM THAT IT REPRESENTS

A. There Is No Consensus Religious View Regarding the Morality and Religious Implications of Physician-Assisted Dying

Petitioner and *amici* such as the United States Conference of Catholic Bishops *et al.*, argue that the Attorney General's directive is consistent with age-old religious views on physician-assisted dying. Gov't Br. at 23; Br. of U.S. Conf. of Catholic Bishops *et al.* at 2. In so asserting, they effectively presume that the entirety of the American religious community, as well as most of Western civilization,

considers physician-assisted dying to be immoral. That presumption is ill-founded and erroneous.

As the discussion above in Part I.A. explains, belief in the preservation of life at all costs are hardly uniform across all religions or even across all adherents of any given religion. As the Supreme Court has emphasized, and as the very existence of the ODWDA itself demonstrates, there is a great deal of debate and divergence of views with regard to this issue. The great diversity in religious and moral thought on physician-assisted dying is matched only by the great diversity of religious faiths in this country.

- Although the Catholic Church may frown upon physician-assisted dying on the one hand, the United Church of Christ and the Unitarian Universalist Association support an individual's right to choose this option.
- Various branches of Judaism also teach sympathy, understanding, and respect for those choose assistance in dying.
- The Presbyterian and Methodist Churches have similarly endorsed respect for the terminally ill patient's choices about how to die.
- And even within faiths, many congregants disagree about the morality of physician-assisted dying, with many supporting it as a legitimate and moral choice. Indeed, even a majority of Catholics support physician-assisted dying.

The Attorney General's Directive overlooks this diversity of religious thought (as well as the similar diversity of medical views addressed by other *amici*) and simply imposes the views of one group on all in violation of religious freedom.

B. The ODWDA Protects the Rights of the Terminally Ill and Affords All of Oregon's Citizens to Exercise Their Religious Freedom Consistent with Their Own Beliefs

Amici such as the Catholic Medical Association and the Christian Medical Association *et al.*, argue that the practice

of medicine necessarily must protect the right to preserve life at all costs and in any event must protect the disabled. The *amici* for Petitioner thus suggest that no one could reasonably seek physician-assisted dying as a legitimate form of "medical care." Br. of Catholic Med. Ass'n at 8-10; Br. of Christian Med. Ass'n at 6; *see also* Br. of Americans United for Life at 10-16; Br. of Not Dead Yet *et al.*, *passim*; Br. of Liberty Counsel at 3-7, 17-18.

These *amici* are wrong. There is no consensus of thought on these issues: Many believe that physician-assisted dying, under very controlled circumstances, in fact *protects* the rights of the terminally ill by honoring their interests in personal autonomy and dignity and by honoring their personal and spiritual beliefs about the end of life.

> Individuals of different religious faiths make different judgments and choices about whether to live on under such circumstances. . . . Allowing the individual, rather than the State, to make judgments "about the quality of life that a particular individual may enjoy" does not mean that the lives of terminally ill, disabled people have less value than the lives of those who are healthy. Rather, it gives proper recognition to the individual's interest in choosing a final chapter that accords with her life story, rather than one that demeans her values and poisons memories of her.

Glucksberg, 521 U.S. at 746-47 (Stevens, J., concurring) (citations omitted).

Many also believe that, in addition to protecting the interests of the terminally ill and honoring their beliefs, the assistance of a physician in ending one's pain and suffering peacefully through the prescription of medication does qualify as legitimate and professional medical practice. *See, e.g.*, Boozang, *supra*, at 565-98; Urofsky, *supra*, at 919-20. Terminally ill patients seeking to end their lives through the assistance of a physician do so not only because of the physical pain they suffer but also because of the mental and psychological toll of terminal illness and because of their fundamental interests in preserving their own autonomy and

dignity in a manner that comports with their personal and spiritual beliefs. They seek their physicians' aid in this endeavor not just for their ability to prescribe medication but also for their succor and support. "[T]he Court [has] recognized that the good physician is not just a mechanic of the human body whose services have no bearing on a person's moral choices, but one who does more than treat symptoms, one who ministers to the patient. This idea of the physician as serving the whole person is a source of the high value traditionally placed on the medical relationship." *Glucksberg*, 521 U.S. at 779 (Souter, J., concurring) (citations omitted).

C. The States Should Be Allowed to Decide for Themselves How to Weigh Their Citizens' Religious and Other Interests Against Any Feared Problems from Physician-Assisted Dying

Amici such as the Thomas More Society and the United States Conference of Catholic Bishops *et al.* protest that the ODWDA will lead our society down a slippery slope to a parade of horribles and that the Attorney General was therefore authorized to regulate physician-assisted dying. Br. of Thom. More Soc'y at 19-26; Br. of U.S. Conf. of Catholic Bishops *et al.* at 12-18.

The Court has rejected many such "parade of horribles" and "slippery slope" arguments before, however, and with good reason. *See, e.g.*, *Atwater v. City of Lago Vista*, 532 U.S. 318, 353 n.25 (2001); *Whalen*, 429 U.S. at 600-602. As the Court in *Glucksberg* recognized, it is up to the states to establish and enforce adequate safeguards to protect against such a parade of horribles. "We agree that the case for a slippery slope has been made out, but—bearing in mind Justice Cardozo's observation of '[t]he tendency of a principle to expand itself to the limit of its logic,'—we also recognize the reasonableness of the widely expressed skepticism about the lack of a principled basis for confining the right." 521 U.S. 733 n.23.

With regard to questions involving the right to die, "[a] State is entitled to guard against potential abuses in such situations." *Cruzan*, 497 U.S. at 281. Indeed, as Justice O'Connor stated, "[t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring). Accordingly, the people of Oregon, as is their prerogative, have decided that their interests in human dignity, individual autonomy, and religious and spiritual freedom outweigh the potential problems of physician-assisted dying and have decided which safeguards they believe are necessary to allow people to leave life in the way that best comports with their beliefs.

* * * * *

As *amicus* Reverend Ken Phifer reflected on his own experience in counseling a terminally ill member of his congregation when she decided to hasten her own death:

> [D]octors cannot always be healers. Each of us will come to a point in life when no medical treatment will help us, save perhaps to relieve our pain. At that point, when our condition is terminal, what we need more than anything else is intelligent compassion. We need people who understand the pain in our bodies and the suffering in our souls. Compassion may well be to give us drugs and apply therapies to make our bodies feel better. But for some of us, compassion may well be to help ease us into death.

Rev. Kenneth W. Phifer, A Hastened Death, Presentation at the Final Exit Network Conference (Nov. 14, 2004), *available at* http://www. finalexitnetwork.org/hastened_ death.htm.

CONCLUSION

For the foregoing reasons, the *Amici Curiae* respectfully request that the judgment of the Ninth Circuit be affirmed.

Respectfully submitted,

GREGORY A. CASTANIAS
(*Counsel of Record*)
LAWRENCE D. ROSENBERG
EMILY M. MORRIS
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
(202) 879-3939

Counsel for Amici Curiae

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APPENDIX

IDENTIFICATION OF *AMICI CURIAE*

THE AMERICAN ETHICAL UNION ("AEU") is a national organization of Ethical Culture societies and is part of a humanistic religious and educational movement inspired by the ideal that the supreme aim of human life is working to create a more humane society. The AEU's faith is in the capacity and responsibility of human beings to act in their personal relationships and in the larger community to help create a better world. The AEU's commitment is to the worth and dignity of the individual, and to treating each human being so as to bring out the best in him or her.

THE AMERICAN HUMANIST ASSOCIATION ("AHA"), founded in 1941, is the oldest and largest humanist organization in the nation, dedicated to ensuring a voice for those with a positive, nontheistic outlook. Humanism is a progressive philosophy of life that, without supernaturalism, affirms the ability and responsibility of human beings to lead ethical lives of personal fulfillment that aspire to the greater good of humanity. The mission of the AHA is to promote the spread of humanism, raise public awareness and acceptance of humanism, and encourage the continued refinement of the humanist philosophy.

AMERICANS FOR RELIGIOUS LIBERTY ("ARL") is a nonprofit public interest educational organization, founded in 1982, dedicated to defending religious liberty, freedom of conscience, and the constitutional principle of separation of church and state. ARL has participated as an amicus in other cases in this Court, including *Glucksberg v. Washington* and *Vacco v. Quill.*

THE CONGRESS OF SECULAR JEWISH ORGANIZATIONS ("CSJO") comprises several independent organizations whose unity of purpose is a secular expression of Jewish heritage, with particular emphasis on the cultural and ethical precepts of Jewish learning. The CSJO seeks to forge a Jewish identity that is

grounded in contemporary life and is committed to the social values of justice, peace, and community responsibility.

THE SHALOM CENTER is a national network (with offices in Philadelphia, Pennsylvania) that draws on Jewish wisdom of the past and present to address issues of social justice, peace, healing of the earth, and spiritual search—so as to voice a new prophetic agenda in Jewish, multireligious, and American life.

THE SOCIETY FOR HUMANISTIC JUDAISM ("SHJ"), established in 1969, includes more than fifty communities and is the central body for the Humanistic Jewish Movement in North America. The SHJ assists in organizing and supporting congregations and in providing a worldwide voice for its members, and is dedicated to the promotion of Jewish and humanistic ideals, including human dignity, integrity, tolerance, and equal treatment.

THE UNITARIAN UNIVERSALIST ASSOCIATION is a religious association of more than 1,000 congregations in the United States and Canada. In 1988, the Association adopted a resolution affirming the right to self-determination in dying and supporting the elimination of civil and criminal penalties against those who, under proper safeguards, assist terminally ill patients in selecting the time and manner of their own deaths.

THE UNITED CHURCH OF CHRIST JUSTICE AND WITNESS MINISTRIES is an organization within the United Church of Christ, one of the most diverse Christian churches in the United States that comprises a membership of over 1.4 million. The Justice and Witness Ministries is faith-based movement for peace, justice, equality, and inclusivity, and whose goals are compassion, advocacy and reconciliation.

FATHER JERRY R. ANDERSON, Episcopal Priest and Director of Pastoral Care at the Good Samaritan Hospital in Los Angeles, California.

THE REVEREND J. EDWIN BACON, Rector of the All Saints Episcopal Church in Pasadena, California.

THE REVEREND FRANK BALDWIN, Senior Pastor of the Orinda Community Church of the United Church of Christ, Orinda, California.

RABBI JONATHAN BIATCH, Rabbi of Temple Beth El in Madison, Wisconsin.

THE REVEREND JOHN R. BROOKE, United Church of Christ, President of the Americans for Death with Dignity, and clergy coordinator for the Compassion and Choices proposed legislation in California.

THE REVEREND DOCTOR KEN BROWN, District Executive of the Pacific Southwest District of the Unitarian Universalist Association, Studio City, California.

THE REVEREND PAUL CHAFFEE, United Church of Christ, Executive Director of the Interfaith Center at the Presidio in San Francisco, California.

THE RIGHT REVEREND JOHN BRYSON CHANE, Eighth Bishop of the Episcopal Diocese of Washington, D.C.; Co-Chair of the "Bishops Working for a Just Society" Coalition and of the Episcopal Church's Committee on National Affairs; and board member of the American Friends of the Episcopal Diocese of Jerusalem, the University Council Committee on Religious and Spiritual Life at Yale University, the Episcopal Church Publishing Company, the Virginia Theological Seminary and Collington Retirement Center, Saint Anna's Home, and Saint Mary's Home.

DOCTOR JOSEPH CHUMAN, Leader of the Ethical Culture Society of Bergen County and Professor of Human Rights and Religion at Columbia University.

THE REVEREND DOCTOR JOHN B. COBB, JR., United Methodist Church, Professor Emeritus of Theology at the Claremont (California) School of Theology; Co-Director of the Center for Process Studies; and Co-founder, Progressive Christians Uniting.

THE REVEREND RALPH H. COOK, Unitarian Universalist, retired professor of the Starr King School for the Ministry.

THE REVEREND DONALD FADO, retired pastor of St. Mark's United Methodist Church of Sacramento, California.

THE REVEREND DUANE H. FICKEISEN, Parish Co-Minister of the Unitarian Universalists of the Cumberland Valley in Boiling Springs, Pennsylvania; President of the Priestley Kingsbury Chapter of the Unitarian Universalist Ministers Association; and Co-President of the Unitarian Universalist Clergy Couples Association.

THE REVEREND GLEN HOLMAN, Disciples of Christ, Sacramento, California, and retired Executive Director of the California Council of Churches.

PROFESSOR JOSEPH C. HOUGH, JR., President of the Faculty and William E. Dodge Professor of Social Ethics at the Union Theological Seminary in the City of New York, and ordained minister in the United Church of Christ, Congregational.

THE REVEREND DOCTOR DAVID J. JAMIESON, Conference Minister Emeritus of the Northern California Nevada Conference of the United Church of Christ.

THE REVEREND PAUL KITTLAUS, Assistant Minister of the United Church of Christ in Claremont, California.

THE REVEREND PETER LAARMAN, Executive Director of Progressive Christians Uniting.

PROFESSOR DANIEL MAGUIRE, Professor of Moral Theology at Marquette University (a Jesuit Catholic institution of higher education).

RABBI BONNIE MARGULIS, rabbi of Reform Judaism.

THE REVEREND WILLIAM MCKINNEY, United Church of Christ, President of and Professor of American Religion at the Pacific School of Religion in Berkeley, California.

THE REVEREND DOCTOR RALPH M. MERO, JR., Unitarian Universalist, founder of Compassion in Dying and member of the national staff of the Unitarian Universalist Association in Boston, Massachusetts.

THE REVEREND AMY ZUCKER MORGENSTERN, Parish Minister of the Unitarian Universalist Church of Palo Alto, California.

THE REVEREND DOCTOR WILLIAM R. MURRY, former President of the Meadville Lombard Theological School in Chicago, Illinois, and Editor of The Journal of Liberal Religion.

THE REVEREND DOCTOR KENNETH W. PHIFER, Senior (and soon-to-be Emeritus) Minister of the First Unitarian Universalist Congregation of Ann Arbor, Michigan; member of the Human Subject Review Committee of the University of Michigan Medical School; and founder of the Interfaith Roundtable.

THE REVEREND DOCTOR GEORGE V. PIXLEY, American Baptist theologian and retired missionary and former Resident Scholar of the Institute for Ecumenical and Cultural Research.

THE REVEREND DOCTOR GEORGE F. REGAS, Rector Emeritus of the All Saints Episcopal Church in Pasadena, California.

THE REVEREND DOCTOR PATRICIA S. ROSS, Senior Minister at the First Congregational United Church of Christ in Portland, Oregon.

THE REVEREND LAROLD K. SCHULZ, retired pastor in the United Church of Christ.

THE REVEREND DOCTOR PAUL D. SIMMONS, Baptist, Director of the Center for Ethics: Ministry, Business, and Medicine, Clinical Professor of Family and Geriatric Medicine, and Adjunct Professor of Philosophy, University of Louisville and Louisville Presbyterian Seminary; Trustee of Americans United for Separation of Church and State, and

member of the Religious Consultation on Population, Reproductive Health and Ethics; the American Society of Law, Medicine and Ethics; the American Society for Bioethics and the Humanities; American Academy of Religion; and the Society for Christian Ethics.

THE RABBI SUZANNE SINGER, Rabbi of Temple Sinai, First Hebrew Congregation in Oakland, California.

THE REVEREND DOCTOR PAUL SMITH, Senior Minister of the First Presbyterian Church of Brooklyn; Vice Chairperson of the Board of Directors of the Arthur Ashe Institute for Urban Health; and member of the Board of Regents of the Long Island College Hospital.

THE RIGHT REVEREND JOHN SHELBY SPONG, retired Bishop of the Episcopal Diocese of Newark, New Jersey, and 2000 William Belden Noble Lecturer, Harvard University.

RABBI JOSHUA STAMPFER, Rabbi Emeritus of the Congregation Neveh Shalom, Portland, Oregon; Adjunct Associate Professor of Urban Studies & Planning - Urban & Public Affairs and Portland State University; and Appointee to the Oregon Government Ethics Commission.

THE REVEREND RON STIEF, Minister and Team Leader of the Washington Office of the United Church of Christ Justice and Witness Ministries.

THE REVEREND JERALD M. STINSON, Senior Minister of the First Congregational Church, United Church of Christ, in Long Beach, California.

RABBI ARIEL STONE, Rabbi of Congregation Shir Tikvah in Portland, Oregon.

THE REVEREND DEBORAH STREETER, Associate Conference Minister of the Northern California Nevada Conference of the United Church of Christ.

THE REVEREND DOCTOR DAVID THOMPSON, Senior Pastor and Head of Staff at the Westminster Presbyterian Church in Sacramento, California.

JANET K. VANDEVENDER, ESQUIRE, Chair of the Board of Directors of the Southern California Nevada Conference for the United Church of Christ.

THE REVEREND CARLTON VEAZEY, Minister of the National Baptist Convention, U.S.A., and Pastor of the Fellowship Baptist Church in Washington, D.C.

RABBI ARTHUR WASKOW, Director of The Shalom Center in Philadelphia, Pennsylvania, and author of many books on U.S. public policy and on Jewish and spiritual life.

THE REVEREND JUDY CLYMER WELLES, Parish Co-Minister of the Unitarian Universalists of the Cumberland Valley in Boiling Springs, Pennsylvania, and Vice-President of the Graduates Association of the Starr King School for the Ministry in Berkeley, California.

THE REVEREND DOCTOR RAY WELLES, retired pastor in the United Church of Christ; semi-retired church consultant; and spiritual counselor.

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IN THE
Supreme Court of the United States

ALBERTO R. GONZALES,
ATTORNEY GENERAL, *ET AL.*,
Petitioners,

v.

STATE OF OREGON, *ET AL.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

SEAN H. DONAHUE
2000 L. Street, Suite 808
Washington, DC 20036
(202) 466-2234

DAVID T. GOLDBERG
Counsel of Record
99 Hudson Street, 8th Fl
New York, N.Y. 10013
(212) 334-8813

DANIEL N. ABRAHAMSON
Drug Policy Alliance,
Office of Legal Affairs
717 Washington St.
Oakland, CA 94607
(510) 208-7711

Attorneys for Amicus Curiae

TABLE OF CONTENTS

Table of Authorities iii

Interest of *Amicus Curiae* 1

Summary of Argument 1

ARGUMENT 3

I. It Is Impossible To Construe The CSA As Vesting The Attorney General With The Broad Power Claimed 3

A. Congress Did Not Confer The Authority On Which The Directive Is Premised 3

B. The Meaning of "Illegitimacy" Must Be Anchored To The Statute's Text And Purposes 10

C. The 1984 Amendment Did Not Confer Power To Overrule State Policy Judgments Unrelated To Controlled Substances 13

II. The CSA Must Be Read As Preserving States' Role In Matters of Public Health And Medical Practice 14

A. Public Health Is Served By Legal Principles Allowing Experimentation And Diversity At the State Level 14

B. Oregon's Law Is A Legitimate and Important Policy "Experiment" 17

C. The Extent and Benefits of Regulatory Diversity Is Significant 18

D. Congress Did Not Intend The CSA To Standardize Medical Practice Nationwide 20

III. Sustaining The Assertion of Authority Would Interfere With Proper Health Care 24

A. The Directive Will Worsen Existing, Serious Inadequacies in End-of-Life Care 26

B. The Authority Claimed, If Approved, Would Chill Legitimate Medical Practice And Distort the Process By Which Controversial Policy Questions Are Resolved 29

CONCLUSION 30

TABLE OF AUTHORITIES

CASES

Alden v. Maine, 527 U.S. 706 (1999) 16

Bates v Dow Agrosciences, LLC, 125 S. Ct. 1788 (2005) 4, 14

BMW N. America v. Gore, 517 U.S. 559 (1996) 21

California Retail Liquor Dealers Ass'n. v. Midcal Aluminum, Inc., 445 U.S. 97 (1980) 15

Chevron U.S.A. Inc. v. NRDC, Inc., 467 U.S. 837 (1984) .. 6

Crandon v. United States 494 U.S. 152 (1990) 6,7

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) 25

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) 4

Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528 (1985) 16

Gonzales v. Raich, 125 S. Ct. 2197 (2005) 24

Gregory v. Ashcroft, 501 U.S. 452 (1991) 15,16

In re Harline, 65 Fed. Reg. 5,665 (Feb. 4, 2000) 9

Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707 (1985) 20

Linder v United States, 268 U.S. 5(1925) 14

McCulloch v. Maryland, 19 U.S. 316 (1819) 16

Medtronic v. Lohr, 518 U.S. 470 (1996) 15, 16

Mississippi Band of Choctaw Indians v. Holyfield, 490 U.S. 30 (1989) 21

New State Ice Co. v. Liebmann, 285 U.S. 262 (1932) 16, 17, 24

Pegram v. Herdrich, 530 U.S. 211 (2000) 4, 14, 15

Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355 (2002) 12, 15, 21

Solid Waste Agency of Northern Cook County v. Army Corps of Engineers, 531 U.S. 159 (2001) ... 4, 14, 16

Tesauro v. Perrige, 650 A.2d 1079 (Pa. Super. Ct. 1994) 22

Tobash v. Jones, 213 A.2d 588 (Pa. 1965) 22

Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002) 10, 25

United States v. Bass, 404 U.S. 336 (1971) ... 4, 14, 15, 16

United States v. Lopez, 514 U.S. 549 (1995) 16

United States v. Moore, 423 U.S. 122 (1975) ..... *passim*

United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975) 23

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001) 23, 24

United States v. Touby, 500 U.S. 160 (1991) 6

Vacco v. Quill, 521 U.S. 793 (1997) ..... *passim*

Washington v. Glucksberg, 521 U.S 702 (1997) .... *passim*

Webb v. United States, 249 U.S. 96 (1919) 9

STATUTES AND LEGISLATIVE MATERIALS

21 U.S.C. § 802(21) 5, 6, 21

21 U.S.C. § 811(a) 6

21 U.S.C. § 811(b) 5, 9, 26

21 U.S.C. § 811(c) 6

21 U.S.C. § 812(b) 6, 8, 24

21 U.S.C. § 823(f) 21

21 U.S.C. § 829 ..... 6, 7

21 U.S.C. § 841 ..... 8, 23

21 U.S.C. § 903 ..... 5, 7, 14, 23

42 U.S.C. § 290bb 6

42 U.S.C. § 1395 15

42 U.S.C. § 1395cc(f) 20

H.R. Rep. 91-1444 (1970) 5, 8

H.R. Rep. 93-884 (1974) 6

S. Rep. 98-225(1984) 14

FEDERAL ADMINISTRATIVE MATERIALS

21 C.F.R. § 1306.04(a) 6, 7, 26

37 Fed. Reg. 16,503 (1972) 15

51 Fed. Reg. 17,476 (May 13, 1986) 9

58 Fed. Reg. 4,898 (Jan. 19, 1993) 13

66 Fed. Reg. 56,607 (Nov. 9, 2001) ..... *passim*

Exec. Order 13,237 (Nov. 28, 2001) 4

STATE STATUTES AND REGULATIONS

Cal. Health & Safety Code § 24185 20

Cal. Health & Safety Code §125300 20

Mich. Comp. Laws § 333.16274 20

N.J. Stat.§ 26:2Z-220 20

N.D. Cent. Code § 12.1-39 20

Or. Rev. Stat. § 127.855 17

Or. Rev. Stat. § 127.865 17

OTHER AUTHORITIES

Acupuncture as Illegal Practice of Medicine,
72 A.L.R.3d 1257 (1976) 19

AMA Council on Ethical & Jud. Affairs, *Physician Participation in Capital Punishment*,
270 JAMA 365 (1993) 13

APHA Policy 8123: Death With Dignity 1

Bernabei et al., *Management of Pain in Elderly Patients with Cancer*,
279 JAMA 1877 (1998) 27

Boumil & Elias,
The Law of Medical Liability (1995) 22

Carson et al., *The Impact of Laws on HIV and STD Prevention*, 30 J. L. Med. Eth. 139 (2002) 19

Chin et al., *Legalized Physician-Assisted Suicide in Oregon – The First Year's Experience*,
340 New Eng. J. Med. 577 (1999) 18

Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Texas L. Rev. 1321 (2001) 16

Cleeland et al., *Pain Management in Minority Patients With Cancer*, 127 Annals Internal Med. 813 (1997) 27

Cohen, *Holistic Health Care: Including Alternative and Complementary Medicine In Insurance and Regulatory Schemes*, 38 Ariz. L. Rev 83 (1996) 19

Davidson, *Pain and Opiophobia*, 40 Healthcare Forum J. 64 (1997). 29

Emergency Contraception Pharmacy Program, *Emergency Contraception* (http://www.ec-help.org) 20

Farber-Langendoen & Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, Annals Internal Med., Mar. 21, 2000 10

Federation of State Medical Boards of the United States, *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004) 29

Ganzini et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care Since The Passage of the Oregon Death With Dignity Act*, 285 JAMA 2363 (2001) 18

Gostin, *Public Health Theory and Practice in the Constitutional Design*, 11 Health Matrix 265 (2001) ... 17

Groopman, *Separating Death From Agony*, N.Y. Times, Nov. 9, 2001, at A21 28

Haugen, *Pain Relief for the Dying: The Unwelcome Intervention of the Criminal Law*, 23 Wm. Mitchell L. Rev. 325 (1997) 28

Hill, *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287 (1996) 28

Hedberg et al., *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 New Eng. J. Med. 961 (2003) ... 18

Hodge, *The Role of New Federalism and Public Health Law*, 12 J.L. & Health 30 (1998) 17

Hyman, *Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment*, 24 J.L. Med. & Ethics 338 (1996) .. 29

Institute of Medicine, Approaching Death: Improving Care at the End of Life (Field & Cassel, eds. 1997) 11, 27

Johnson, *Disciplinary Actions and Pain Relief: An Analysis of the Pain Relief Act*, 24 J.L. Med. & Ethics 319(1996) 27

Kapp, *Treating Medical Charts Near the End of Life: How Legal Anxieties Inhibit Good Patient Deaths*, 28 U. Tol. L. Rev. 521 (1997) 28

Kimsma, *Euthanasia and Euthanizing Drugs in The Netherlands*, in Drug Use in Assisted Suicide and Euthanasia (Battin & Lipman eds., 1996) 10

Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. Med. & Ethics 332 (1998) 27, 28

Meier et al, *A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 N Eng. J. Med. 1193 (2001) 26

Midwives Alliance of North America, *Direct-Entry Midwidery State-byState-Legal Status* (Http://www.mana.org/statechart.html) 19

Morgan, *American Opiophobia: A Customary Underutilization of Opioid Analgesics*, in Controversies in Alcoholism and Substance Abuse (Stimmel, ed. 1986) 25

National Conf. Of State Legislatures, *State Laws on Heart Attacks, Cardiac Arrest & Defibrillators* (http://www.ncsl.org/programs/health/aed.htm) 19

National Institutes of Health, *Acupuncture: NIH Consensus Statement* 15(5):1-34 (1997) 19

9 Oxford English Dictionary (2d ed. 1989) 11

Oken, *Curing Healthcare Providers' Failure to Administer Opiods in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917 (2002) 25

Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective*, 24 J.L. Med. & Ethics 296 (1996) 29

The Random House Dictionary of the English Language (2d ed. 1987) 11

Sabatino, *Removing Legal Obstacles to Effective Pain Management*, NAELA Q., Spring 2001 27

Schwartz, *Where Everybody Knows Your Name: Iowa's Policy of Name-Based HIV Reporting*, 7 J. Race & Gender Just. 387 (2003) 19

SUPPORT Principal Investigators, *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591 (1995) 27

Teno et al., *Persistent Pain in Nursing Home Residents*, 285 JAMA 2081 (2001) 27

Von Roenn et al., *Physician Attitudes and Practices in Cancer Pain Management*, 119 Annals Internal Med. 121 (1993) 27

Whitney et al, *Views of U.S. Physicians and Members of the AMA House of Delegates on Physician-Assisted Suicide*, 16 J. Gen. Intern. Med. 290 (2001) 12

Interest of *Amicus Curiae*[*]

Founded in 1872, the American Public Health Association (APHA) is the oldest, largest and most diverse organization of public health professionals in the world. The association aims to protect all Americans and their communities from preventable, serious health threats and strives to assure community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. APHA represents a broad array of health providers, educators, environmentalists, policy-makers and health officials at all levels working both within and outside governmental organizations and educational institutions.

Based on the values of health, equity, diversity, empowerment, integrity, dignity, and knowledge for individuals and communities, APHA advocates the conditions for a healthy society, promotes the scientific and professional foundation of public health practice and policy, and supports its members in promoting and protecting environmental and community health.

In the context of treatment refusal, APHA has recognized that "to the seriously ill and infirm, death is not only a distinct possibility, but sometimes preferable to any alternative," and that health care policy "should not blindly stress the continuation of life." APHA Policy 8123: Death With Dignity. APHA does not take a position on whether Oregon's law is wise policy. APHA believes, however, that sustaining the Attorney General's Directive would adversely affect the public health and submits this brief to set forth its concerns.

Summary of Argument

Although this case arises from the Attorney General's attempt to pretermit State-level policies respecting physician-

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[*]No counsel for any party authored any part of this brief. No person or entity other than *Amicus* and its counsel made a monetary contribution toward submission of this brief, which is filed with the parties' written consent.

assisted suicide, the authority asserted would sweep much further. Underlying the Directive is a claim that Congress delegated to the Attorney General broad powers to regulate the practice of medicine – and to take action against a physician for prescribing a controlled drug in the course of a medical practice the Attorney General disapproves of, even if the practice is affirmatively authorized and closely regulated by the licensing State, and even if the grounds for objection are unrelated to the possibility that drugs will be diverted or abused.

It is not only implausible that Congress *would* vest such a power in the Attorney General – but impossible to construe the statute he points to, the Controlled Substances Act (CSA), as having conferred it. Everything about that statute attests that it was enacted to address a nationally important, but discrete public health problem: the diversion and abuse of certain drugs. And everything in the Act's text and structure confirms that the Attorney General's responsibility is confined to assuring that Congress's means of addressing the problem – a closed distribution system – would operate effectively.

The regulatory regime the Attorney General asks the Court to approve also ignores the important and conspicuous public health benefits that result from entrusting matters of medical regulation and health policy to State-level resolution. As the opinions in *Glucksberg* and *Quill* eloquently attest, this long-established allocation of decision making power is working exceptionally well with respect to the very issue that is the subject of the Directive. The text of the CSA indicates that Congress meant to preserve the benefits of State regulation, and nothing in the Act's text or structure suggests that, by recognizing the intrastate dimension of the national *drug trafficking* problem, Congress intended to establish – or permit – a system of uniform *medical practice* regulation, under the Attorney General.

The Directive – and the assertion of power underlying it – carry further public health dangers. As this Court has

recognized, *patients* are harmed when physicians are deterred from providing care in accord with their professional judgment – and the possibility of intervention by law enforcement agents has a uniquely potent distorting effect on medical practice. These deterrent effects are of special concern because inappropriate *undertreatment* with controlled drugs, and inadequate pain relief for those who are terminally ill, are recognized to be public health problems of the first order. By establishing a broad and ill-defined federal law enforcement role in fields of medical practice where there is no suggestion of drug diversion or illicit physician behavior – and no claim that States are defaulting on their closed system responsibilities – the Attorney General's construction of the statute could only impede the provision of legitimate, medically appropriate care.

Sustaining the Directive would also adversely affect the *process* by which difficult, controversial, and profound policy decisions are made. Experimentation, evidence-gathering, and persuasion at the State level and in Congress are difficult; "interpretive rules," by contrast, may issue – as this one largely did – without the involvement or even awareness of those with opposing views and those most directly affected. Given the many matters that engender comparably strong objections (and that also happen to include administration of controlled drugs) sustaining the assertion of authority here would surely make pursuit of similar administrative declarations of "illegitimacy" the first resort – and the pull and haul of the lawmaking process the Constitution contemplates, a distant second choice.

ARGUMENT

I. It Is Impossible To Construe The CSA As Vesting The Attorney General With The Broad Power Claimed

A. In Enacting The CSA, Congress Did Not Confer The Authority On Which The Directive Is Premised

Although the Directive addresses the specific practice of physicians' assisting terminally ill patients to hasten death, the power claimed would extend to *any practice* in which

controlled substances are prescribed – and would include authority to pass judgment on controversial matters of medical practice and ethics, irrespective of whether the controversy (or the Attorney General's objection) has anything to do with the use of controlled (as opposed to other) substances. Moreover, the Attorney General would be empowered to bring within the ambit of federal *criminal* law medical practices affirmatively authorized and actively supervised by the licensing State.

Not only must this assertion of authority reckon with the presumption that Congress does not intend drastically to alter the federal/State balance in matters, historically entrusted to the States, see, *e.g.*, *United States v. Bass*, 404 U.S. 336, 349 (1971); *Bates v Dow Agrosciences, LLC*, 125 S. Ct. 1788,1801 (2005), *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000), but it must overcome the fundamental implausibility that Congress *would* delegate power to resolve large and momentous questions of ethical and medical legitimacy, see *SWANCC v. Army Corps of Eng'rs*, 531 U.S. 159, 172 (2001); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120,133 (2000), let alone to an official with no recognized expertise in matters of public health or medical practice.[1]

Far from "manifesting" an intent to confer such extraordinary authority, the text and structure of the CSA rule out the construction advanced, and make clear that Congress intended a more limited, but still vital responsibility for the Attorney General: maintaining the "closed system" for

[1]In fact, the federal government rarely undertakes even to *examine* questions of such complexity and moment – let alone answer them definitively for the Nation – without involving those in fields whose knowledge and experience span a far broader range than does the Attorney General's. See, *e.g.*, Exec. Order 13,237 (Nov. 28, 2001)§ 3(a) (President's Council on Bioethics "shall include members drawn from the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences"); see also *id.* § 2(a)(5)(c) (noting "the complex and often competing moral positions" on issues and directing Council to resist "an overriding concern to find consensus").

distributing certain drugs, H.R. Rep. 91-1444 at 6 (1970), and assuring that individuals who would subvert or undermine that system do not succeed.

Thus, instead of evincing intent to centralize authority over medical practice, the CSA includes an express disclaimer of broad preemptive effect, 21 U.S.C. § 903, and expressly affirms the States' longstanding role as regulators of medical practice within their borders. See *id.* § 802(21) (defining "practitioner" to include "a physician * * * licensed by * * * the jurisdiction in which he practices to distribute [or] dispense * * * a controlled substance in the course of professional practice"). In fact, until Congress amended the Act in 1984, the Attorney General was not even *permitted* to deny registration based on a practitioner's active, improper dispensing of controlled drugs, unless the licensing State took decisive disciplinary action (or he was convicted of a felony). See *United States v. Moore*, 423 U.S. 122, 141n.19 (1975) (registration was "a matter of right" for individual "engaged in activities involving these drugs which are authorized or permitted under State law'") (quoting H.R. Rep. 91-1444 at 23).

Nor do the statutory text and structure detract from the intuitive unlikelihood of the notion that Congress would vest *the Attorney General* (or the DEA, as designee) with authority to make plenary, nationwide judgments concerning difficult, even profound questions of medical practice "under the CSA." Rather, the statute's terms and legislative history attest to Congress's concern about the Attorney General's involvement in even mundane medical decision making. See, *e.g.*, 21 U.S.C. § 811(b) ("The recommendations of the [HHS] Secretary * * * shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance"). In the one instance when Congress authorized formulation of federal standards of "professional practice" – with respect to "the

medical treatment of * * * narcotic addition," 42 U.S.C. § 290bb – it entrusted that responsibility to the HHS [then HEW] Secretary. See H.R. Rep. 93-884 (1974) ("All decisions of a medical nature are to be made by the Secretary. Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General").

Indeed, the narrow lawmaking powers Congress did confer on the Attorney General are carefully cabined. Title 21 U.S.C. § 811(a) requires that decisions to place substances on the federal schedules be made through formal rulemaking pursuant to the Administrative Procedure Act; § 811(c) specifies the eight factors that must be considered in scheduling a drug; and 21 U.S.C. § 812(b) specifies findings that must be made before he may assign a drug to a particular schedule. See generally *United States v. Touby*, 500 U.S. 160, 166 (1991).

The Attorney General nonetheless contends that the structure of the CSA supports an overarching "legitimate medical practice" limitation, and that the authority asserted here, to pass judgment on what is "legitimate" "under the CSA," is essentially the same one recognized in *Moore* (and in earlier cases sustaining convictions of physicians under predecessor statutes).

At the outset, the phrase the Attorney General most thoroughly parses and identifies as the principal source of authority for the Directive – "legitimate medical purpose" – derives from a Justice Department *regulation*, see 21 C.F.R. § 1306.04(a), not the text of the relevant *statutory* provision. Compare 21 U.S.C. § 802(21); *id.* § 829(a)-(b) (exempting prescriptions "in the course of professional practice" from the Act's reach); see *Chevron U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984) (ambiguous language *in a statute* may be treated as a delegation by Congress of interpretive authority to the agency administering the law); but cf. *Crandon v. United States* 494 U.S. 152, 177 (1990) (Scalia, J., concurring) (for purposes of

deference, prosecutor does not "administer" the criminal statute under which she proceeds). Moreover, that regulation, by its terms, addresses only what qualifies as a "valid *prescription*," 21 C.F.R. § 1306.04(a), under the CSA – though Congress expressly provided that physicians may dispense controlled substances directly to patients *without* a written prescription. See 21 U.S.C. § 829(a), (b).[2]

But accepting, as *Moore* did, that Congress contemplated keeping "medical practice within accepted limits," 423 U.S. at 142, *in order to prevent drug trafficking*, does not establish that the statute should be construed as conferring a *plenary* power to decide that particular medical practices are not "legitimate" – and then treat as federal drug offenders doctors who prescribe controlled drugs in the course of the Attorney-General-disapproved practice.

The Court in *Moore* did not *defer* to an administrative definition of what constitutes proper medical practice: the case was a criminal prosecution, see *Crandon*; and the government assumed the burden of proof, which it carried by presenting "expert medical testimony," 505 F.2d at 426 (McKinnon, J., dissenting), that the defendant had completely abandoned his professional responsibility to his "patients." There was no claim that Moore's conduct – prescribing "some 800,000 methadone tablets" over a four-month period, 423 U.S. at 126, and charging patients "according to the number of tablets desired," *id.* at 143 – was affirmatively authorized under State [District of Columbia] law.[3]

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[2]Although *Oregon law* requires a written prescription, it cannot fairly be said that this "exception" is "not relevant here," Pet.Br.3. It highlights the unsoundness of the Attorney General's construction: if the provision were intended to authorize overruling policy choices like Oregon's, it is hard to understand why Congress would have the Attorney General's power depend on whether a State's implementing legislation required a written prescription – with States that opted *against* such a patient-protective requirement enjoying *broader* latitude. Cf. 21 U.S.C. § 903.

[3]The nature of the prosecution's evidentiary burden was not decided by

The "illegitimacy" at issue in *Moore* was the very one that Congress sought to combat in enacting the CSA: selling controlled drugs, "'primarily for the profits to be derived therefrom,'" *id.* at 135 (quoting H.R. Rep. 91-1444 at 10), to those seeking them for their prohibited properties. See *id.* at 143 (defendant "acted as a large-scale 'pusher' not as a physician"). The authority to prosecute was a necessary incident of Congress's recognition, expressed in the text of the statute, that the closed system for distributing these particular drugs would be defeated if doctors were permitted to exploit their privileged position within the system, to cater the very demand the law was enacted to suppress.

By contrast, the "illegitimacy" asserted here – and the power claimed – are untethered from the text, structure, and purposes of the statute. Although the Attorney General invokes his "ability to administer the Act's comprehensive national scheme for controlling dangerous substances," Pet.Br.14, there is no suggestion that controlled drugs prescribed in compliance with Oregon law are likely, let alone especially likely, to be diverted outside legitimate channels: given the substantial additional regulation the State imposes, the opposite is surely the case. Likewise, given that the relevant patient population is limited to individuals at an advanced stage of terminal illness, it is nearly certain that the considerations that trigger control under the statute, see 21 U.S.C. § 812(b)(2) – apply with *less* force in DWDA prescriptions than in other instances where physicians prescribe Schedule II drugs in professional practice.[4]

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this Court in *Moore*, which addressed whether a rogue doctor could be *charged* under § 841. As explained *infra*, see n.11, even if the opinion's quotation of the jury instructions could be understood as approval, those instructions were – at best – ambiguous on precisely the point the Attorney General asserts they were "clear."

[4]While the Attorney General emphasizes the frequency with which terms such as "medical use," "treatment," and "treatment with severe restrictions" appear in the subsections of § 812, the power claimed draws no distinction between substances on the various schedules or between drugs subject to "severe restrictions," *id.* § 812(b)(2)(B), and those which are not.

Likewise, notwithstanding assertions that helping terminally ill patients hasten their deaths is not a "proper use of a controlled substance," Pet.Br.11, and is illegitimate *"for purposes of the CSA,"* Pet.Br.26 (emphasis added), the Attorney General does not suggest that prescribing a controlled substance to a patient who seeks to hasten death is "illegitimate" *in the same sense* that prescribing morphine to an addict would be, see *Webb v. United States*, 249 U.S. 96 (1919). The "illegitimacy" the Attorney General identifies *has nothing to do with the particular substances prescribed* – or with the particular pharmacological characteristics of those drugs. Cf. *In re Harline*, 65 Fed. Reg. 5,665, 5,670 (Feb. 4, 2000) (noting diversity of medical opinion as to "when it is appropriate to use controlled substances in the treatment of weight control").[5] Thus, the Attorney General acknowledges that "doctors in Oregon [who] dispense substances other than those regulated under the CSA to hasten their patients' deaths," are beyond the Directive's reach, Pet.Br.43; see 21 U.S.C. § 811(b), but does not suggest any *medical* distinction between those doctors' conduct and that which the Directive governs.

Two significant conclusions follow. First, it is hard to imagine that a Congress that *opposed* physician assistance of the kind Oregon has authorized – or even one that simply intended to confer on the Attorney General the authority to regulate medical practices (for reasons unrelated to drug diversion) – would so limit his power to stop practices he has determined to be "[il]legitimate."

Treating substances interchangeably is incongruous with the Act's stringent, schedule-driven limitations on the controls the Attorney General may impose – and on whether he can impose controls at all. See *id.* § 811(b).

[5]The regulatory treatment of Marinol (Pet.Br.30) is no precedent for the power claimed here. The DEA action occurred in the context of a decision rescheduling a particular drug – determined to have "a currently accepted medical use with severe restrictions," 51 Fed. Reg. at 17,476, and, as Petitioners' Brief explains, the restriction was based on "a significant risk" particular to that drug, *id.* at 17,477, *i.e.*, that it would be widely sought on account of its chemical similarity to marijuana, a Schedule I drug.

More important, although the Directive is described as embodying a "broad consensus," Pet.Br.18, none of the authorities cited opposes the "practice" of "assisted suicide [*with controlled substances*]" – or indicates that the pharmacological properties (or legal status) of the particular drug a doctor prescribes is relevant to, let alone determinative of, the "legitimacy" of the practice Oregon authorizes. Indeed, there are strong reasons to expect that many who *oppose* the Oregon law based on conceptions about doctors' proper "role," see *id.*, would *reject* the Directive's implication: *i.e.*, that Oregon physicians who *do* so help their terminally ill patients should confine themselves to substances that do not appear on the federal schedules – even when, as a matter of professional judgment, they believe that these other medications are not in their patients' best interests.[6]

B. The Meaning of "Illegitimacy" Must Be Anchored To The Statute's Text And Purposes

Moore and other cases cited by the Attorney General establish that the meaning of "legitimacy" under the CSA should be defined – and limited – by that which *Congress* recognized as "illegitimate": doctors' "trafficking" or "pushing" drugs (or enabling others to do so). So construed, the Attorney General has all the power needed to accomplish the Act's objectives and fulfill the responsibilities Congress entrusted to him, without compromising States' power to regulate medical practice, or terminating debate and experimentation in the field of public health – or unnecessarily

[6]As the Court of Appeals observed, "controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives." 368 F.3d at 1123 n.5 (citing Kimsma, *Euthanasia and Euthanizing Drugs in The Netherlands*, in Drug Use in Assisted Suicide and Euthanasia 193 (Battin & Lipman eds., 1996); Farber-Langendoen & Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, Annals Internal Med., Mar. 21, 2000, at 482)). Cf. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002) (assuming that physicians do not prescribe "unnecessary medications").

deterring legitimate, beneficial medical practice. See *infra*.

By contrast, the Attorney General's efforts – in the Directive itself and his defense of it in this Court – to formulate a definition of medical "legitimacy" narrow enough to rule out the Oregon-sanctioned practice raises serious problems.

It would seem unrealistic in any event to expect that questions that have engaged, challenged, and divided the Nation's foremost bioethicists – and engendered "earnest and profound debate," 521 U.S. at 735, among its citizenry and health care professionals – could be settled through resort to the dictionary, see Pet.Br.18. But more troubling is the guidance that the Attorney General purports to derive from those sources. Applied literally, the cited definitions would exclude *entire fields* of professional practice – and many medical procedures that are regularly performed, with controlled substances. For example, fertility treatments and cosmetic surgery (and nontherapeutic abortions) are often found *not* to entail "the cure, alleviation, and prevention of disease * * * [or] the restoration and preservation of health," Pet.Br.19 (quoting 9 Oxford English Dictionary 549 (2d ed. 1989)).

Even worse, such dictionary definitions reflect assumptions about the "ends of medicine" that not only are controversial, but are, in important ways, a cause of what all recognize to be a serious public health problem. It is precisely because prescribing pain medication to those who are terminal ill *does not* "'restor[e] or preserv[e] health or due physical condition,'" Pet.Br.19 (quoting The Random House Dictionary of the English Language 1194 (2d ed. 1987)), that medical training, focused on curing disease, long neglected to educate physicians about palliative care. See Institute of Medicine, Approaching Death: Improving Care at the End of Life 207 (Field & Cassel, eds. 1997) ("Deficiencies in * * * education for end-of-life care reflect a medical culture that defines death as failure and ignores care for dying people as a source of professional accomplishment and personal meaning").

Defining "illegitimacy" under the CSA with reference to legal standards governing "medical necessity" in the insurance reimbursement context, see Pet.Br.42, is equally ill-considered. Reimbursement denials carry no intimation of a practice's "illegitimacy." Rather, the rules governing medical necessity – which are decidedly *non*uniform among the States, see *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002) – more often reflect determinations that scarce funds should be first allocated to procedures needed to "restore [policyholders'] health." Of course, many doctors perform procedures despite the unavailability of third-party reimbursement.

Nor does "consensus" (Pet.Br.11) distinguish the subject matter of the Directive from other medical practices on which the Attorney General might have strong views. Even accepting that Congress was interested in suppressing State diversity, but see *infra*, there is, as explained above, *no* consensus in the medical community supporting the regime the Directive would implement – in which Oregon physicians would be permitted to "dispense substances other than those regulated under the CSA to hasten their patients' deaths," Pet.Br.35, but would be harshly penalized for prescribing a controlled substance.

Even at a higher level of generality, opinion is decidedly less one-sided than portrayed. See Whitney et al, *Views of U.S. Physicians and Members of the AMA House of Delegates on Physician-Assisted Suicide*, 16 J. Gen. Intern. Med. 290 (2001) (45% of physicians surveyed answered that physician assistance should "definitely" or "probably" be legal). And although *Glucksberg* and *Quill* made quite clear that proponents of physician assistance do not have legal tradition on their side, see Pet.Br.22 (citing *Glucksberg*, 521 U.S. at 710-719); but cf. *id.* at 716 (noting "many significant changes in state laws and in the attitudes these laws reflect"), it is jarring to see the opinions in those cases – which evinced respect for Oregon's side of the "debate" and presented the DWDA's possible implementation as a constitutionally benign development –

cited as supporting the proposition that "strik[ing] the * * * balance," *id.* at 736 (O'Connor, J., concurring), in favor of patient self-determination is facially "illegitimate."[7]

C. The 1984 Amendment Did Not Confer Power To Overrule State Policy Judgments Unrelated To Controlled Substances

Nor can Congress's 1984 amendment of the CSA (see Pet.Br.34) plausibly be construed as conferring the sweeping powers asserted by the Attorney General. First, that measure's enactment calls attention to a basic problem in the Attorney General's *principal* claim: it is not easily understood why a Legislature that intended to authorize the Attorney General to overrule affirmative State policy judgments on grounds *unrelated* to drug-diversion and abuse (via the purported "delegation" of power to judge "medical legitimacy") would have enacted a law making a State's *inaction* against an individual practitioner who was, in fact, diverting controlled drugs, binding on the Attorney General, see p.5, *supra*.

More important, the text, structure, and legislative history of the law, passed as the "Dangerous Drug Diversion Control Act," make clear that Congress intended the Attorney General to "continue to give deference to the opinions of state licensing

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[7]It bears mention that the Justice Department has elsewhere *refused* to adopt precisely the same understanding of "medical practice" that is asserted to require overruling of Oregon's judgment. Many of the same organizations whose condemnation of "physician-assisted suicide" the Directive relies upon have denounced physician involvement in administering *capital punishment* as "illegitimate" – *on the same ground, i.e.*, as contrary to the physician's role as "healer," see AMA Council on Ethical & Jud. Affairs, *Physician Participation in Capital Punishment*, 270 JAMA 365 (1993). But the Justice Department has disagreed. See 58 Fed. Reg. 4,898 (Jan. 19, 1993) (declining to bar physician participation). While there is plainly no inherent contradiction in supporting capital punishment while opposing Oregon's approach to decisional autonomy at the end of life as a *policy matter*, this inconsistency highlights that disagreement with Oregon – which does not sound in drug control or law enforcement – also does not reflect a consistently adhered-to conception of "legitimate medical practice."

authorities, S. Rep. 98-225 at 262 (1984), and that the measure was addressed at a particular "weakness" in the then-existing enforcement system, *id.* Making registration *entirely* dependent on enforcement actions by often-overburdened and slow-moving State authorities, Congress recognized, raised intolerable risks that practitioners engaged in acts inimical to federal *and* State anti-diversion policy would remain entitled, as of right, to dispense controlled substances until State regulators took action, see *id.*

II. The CSA Must Be Read As Preserving States' Role In Matters of Public Health And Medical Practice

A. Public Health Is Served By Legal Principles Allowing Experimentation And Diversity At the State Level

That "the CSA is binding federal law" (Pet.Br.41) does not cast light on the legal question actually presented here: whether States retain their historic power to regulate medical practice *up to the point* that doing so would conflict with Congress's drug control concerns, or whether the CSA endows the Attorney General with plenary power over *all* medical practice "with controlled substances," with States limited to authorizing those practices which the Attorney General does not object to.

Not only is the former construction far more sensible as a matter of text, structure and legislative intent, see 21 U.S. § 903, but it draws strong support from this Court's precedents, which (1) establish that medical regulation (and public health) has traditionally – and consistently – been a matter of State concern, see, *e.g.*, *Pegram*, 530 U.S. at 237; *Linder v. United States*, 268 U.S. 5, 18 (1925), and (2) require that federal laws be construed so as to preserve, rather than displace, State authority "in areas of traditional state regulation," unless a contrary congressional intent is manifest, *Bates*, 125 S. Ct. at 1801; *Bass*, 404 U.S. at 349 (1971); *SWANCC*, 531 U.S. at 172.

Beyond the irony of invoking the spirit of the *Lochner* dissents – which championed State autonomy and experimentation – in defense of the Directive, the Attorney

General's suggestion (Pet.Br.37, 40) that these rules are relics of a bygone constitutional era is puzzling. The States' primary role in regulating medical practice – and this Court's recognition of it – did not stop with *Linder*. See, *e.g.*, *Pegram*; *Medtronic v. Lohr*, 518 U.S. 470, 475 (1996); *Rush Prudential*, 536 U.S. at 386. Nor has this understanding been idiosyncratic to the judicial branch. See 42 U.S.C. § 1395 ("Nothing in [Medicare program] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided"); 37 Fed. Reg. 16,503, 16,504 (1972) ("[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine").

And as the decisions cited above attest, it is not possible to describe the modern Court's hesitancy to enforce categorical, *constitutional* limitations on congressional power as a rejection of the legal *relevance* of the historic distribution of responsibility. Rather, doctrinal developments evidence a shift in the *means* by which respect for the Constitution's federal structure is expressed: *i.e.*, increasingly through rules of statutory interpretation, which assure that States are not divested of their historic responsibilities without evidence of an deliberate congressional decision to alter the balance. See *Bass*, 404 U.S. at 349 ("the requirement of clear statement assures that the legislature has in fact faced and intended" the consequences for federal system).[8]

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[8]There is a threshold problem with the Attorney General's attempted canon-by-canon refutation – see Pet.Br.44 (asserting inapplicability of anti-preemption presumption); *id.* at 37 (asserting inapplicability of *Gregory* rule): even if *those* rules did not govern, this Court has held (in cases not cited in Petitioners' Brief) that a construction fundamentally altering the federal-State balance – that does *not* formally preempt State law or directly regulate State governments – is *also* disfavored. See, *e.g.*, *Bass*, 404 U.S. at 349; cf. *California Retail Liquor Dealers Ass'n. v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980) (federalism concerns require antitrust exception for private anticompetitive conduct that is "clearly authorized" and "actively supervised" by State).

More important are the *reasons* why the Court has not embraced a presumption in favor of displacement. "Treat[ing] the States as * * * joint participants in the governance of the Nation," *Alden v. Maine*, 527 U.S. 706, 748 (1999), "preserves to the people numerous advantages," *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991):

> It assures a decentralized government that will be more sensitive to the diverse needs of a heterogenous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry.

Id. See also *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).[9]

Equally important, while the various federalism-based canons are not identical, neither are they, as this argument presupposes, a set of discrete, disconnected rules. There is no principled reason why an interpretation of federal law that made an Oregon law literally inoperative should be disfavored, but one which "merely" subjected individuals to criminal punishment for carrying out the State's affirmative policy judgment should raise no similar judicial caution. In "sensitive areas," *Bass*, 404 U.S. at 349, such formalisms do not usually control. See *McCulloch v. Maryland*, 19 U.S. 316, 431 (1819) ("the power to tax involves the power to destroy").

[9]One principal rationale for the trend toward restraint in constitutional adjudication – recognition of the ways in which State interests are protected through the Constitution's lawmaking process, see *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 552 (1985); *United States v. Lopez*, 514 U.S. 549, 577 (1995) (Kennedy, J., concurring) – helps explain the more stringent clear statement rule of *SWANCC*. Although Congress is not barred entirely from delegating preemptive power to an administrative agency, see *Medtronic*, 518 U.S. at 495, Congress, not the Executive, must consider the costs to the federal system. See generally Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Texas L. Rev. 1321, 1393 (2001).

This case supplies a vivid illustration of what should *not* happen in a system of government where the States' distinctive constitutional status is taken seriously – and of why the *SWANCC* rule is sound. Although the Attorney General recognizes that Congress imposed stringent procedural limitations on his power to make even minor scheduling decisions – or

These advantages fully characterize the allocation of responsibility over public health, which not only permits recognition of differences in "health needs across the nation," Hodge, *The Role of New Federalism and Public Health Law*, 12 J.L. & Health 309, 356 (1998), and the benefits of policy experimentation, see Gostin, *Public Health Theory and Practice in the Constitutional Design*, 11 Health Matrix 265, 287 (2001) – but also permits a plurality of approaches on matters where disagreement has significant moral, as well as empirical, dimensions.

B. Oregon's Law Is A Legitimate and Important Policy "Experiment"

Oregon's law exemplifies these benefits. In *Glucksberg* and *Quill*, the Court described the continuing State-level debate "about the morality, legality, and practicality of physician-assisted suicide" as a paradigm of what "should [occur] in a democratic society," 521 U.S. at 735. Justice O'Connor's opinion invoked States' "extensive and serious evaluation" as a ground for restraint on the constitutional question presented, see *id.* at 737, and Justice Souter noted that the Court's judgment would allow "experimentation [to] be attempted in some of the States," *id.* at 787, which, in turn would "confirm[] or discredit[] the concerns" about possible abuse, *id.*

Consistent with these expectations, Oregon's decision to strike a different "balance" – to serve as a "laboratory" for the "novel social * * * experiment," of regulated physician-assisted suicide, *New State Ice*, 285 U.S. at 311 – has catalyzed deliberation and action elsewhere, and its experience under the DWDA has informed the public discussion of the subject and promoted the reasoned development of public health policy.

By imposing recordkeeping requirements, see Or. Rev. Stat. § 127.855, and issuing detailed annual reports, *id.* § 127.865,

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revoke the registration of a single practitioner, he did not even give Oregon meaningful *notice* that the rule, purporting to nullify the verdict of two State referenda, was in the offing, let alone afford an opportunity to be heard.

which include demographic information about the patients who have obtained prescriptions and results of interviews with prescribing physicians concerning their patients' circumstances and reasons for requesting prescriptions, Oregon has enabled research on empirical questions that have long figured centrally in the policy debate. For example, researchers have consistently found that experience in Oregon *does not* bear out concerns that physician-assistance "would be disproportionately chosen by or forced on terminally ill patients who were poor, uneducated, uninsured, or fearful of the financial consequences of their illness." Chin et al., *Legalized Physician-Assisted Suicide in Oregon – The First Year's Experience*, 340 New Eng. J. Med. 577, 582 (1999); accord Hedberg et al., *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 New Eng. J. Med. 961 (2003).[10]

C. The Extent and Benefits of Regulatory Diversity Are Significant

The Attorney General's brief, focused narrowly on a single development in a single mode of health regulation – the eclipse of the "locality rule" in medical malpractice litigation (Pet.Br.36), but see p. 21, *infra* – does not begin to capture the extent and importance of ongoing State-level innovation, experimentation, and diversity in health law and policy.

Professional licensure laws continue to reflect substantial interstate differences: "Arizona recognizes and licenses the professions of chiropractic, acupuncture, naturopathy, and homeopathy. The States of Oregon and Utah recognize and license practitioners of chiropractic, acupuncture, and

[10]Research has also cast doubt on predictions that the Act's implementation would adversely affect other aspects of health care for the dying, finding, for example, that a high proportion of Oregon doctors had made efforts to improve their knowledge of pain medications and their recognition of depression and other psychiatric disorders, and were referring more patients to hospice care. See Ganzini et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care Since The Passage of the Oregon Death With Dignity Act*, 285 JAMA 2363 (2001).

naturopathy. The States of Alabama, Illinois, Indiana, Michigan, Minnesota, Mississippi, North Carolina, Oklahoma, South Dakota, and Wyoming, recognize and license only physicians, surgeons and chiropractors." Cohen, *Holistic Health Care: Including Alternative and Complementary Medicine In Insurance and Regulatory Schemes*, 38 Ariz. L. Rev 83 (1996). Midwifery is prohibited in 14 States and the District of Columbia, see http://www.mana.org/statechart.html, while 10 of the 36 States that permit it provide for Medicaid reimbursement.

On the other hand, experiences in "vanguard" States have influenced important changes in the mainstream. For example, acupuncture, once marginalized, has been shown to be effective enough for the National Institutes of Health to call for its expanded use in "conventional medicine," *Acupuncture: NIH Consensus Statement* 15(5):1-34 (1997); compare *Acupuncture as Illegal Practice of Medicine*, 72 A.L.R.3d 1257 (1976).

In some health areas, a single State's innovative policy will meet with rapid acceptance. In 1997, Florida, recognizing the life-saving benefits of defibrillators for people suffering cardiac arrest, was the first State to enact a law broadly encouraging public access to such devices. By mid-2001, all fifty States had adopted similar measures. See http://www.ncsl.org/programs/health/aed.htm. By contrast, other controversial medical practice questions have divided the States for decades. See, *e.g.*, Cohen, 38 Ariz. L. Rev. at 117 (discussing differing States' responses to EDTA chelation treatment).

States have played the central role in fighting emergent health threats, most prominently the HIV epidemic, see Carson et al., *The Impact of Laws on HIV and STD Prevention*, 30 J. L. Med. Eth. 139 (2002), staking out significantly different, often controversial, policy approaches. Compare *id.* at 141 (asserting health benefits of "name-based reporting") with Schwartz, *Where Everybody Knows Your Name: Iowa's Policy of Name-Based HIV Reporting*, 7 J. Race & Gender Just. 387 (2003)

(criticizing such policies on public health grounds).

And States have likewise taken nonuniform approaches to important developments in reproductive medicine, see Nat'l Conf. State Legislatures, *50-State Summary of Laws Related To Insurance Coverage for Infertility Therapy* (describing States' regulation of in-vitro-fertilization); see also http://www.ec-help.org (noting that six States permit women to obtain emergency contraception directly from pharmacies).

The impassioned, ongoing debate over stem cell research have led some States to enact prohibitions on the practice of "therapeutic cloning," while two have passed laws affirmatively encouraging it. Compare, *e.g.*, N.D. Cent. Code § 12.1-39; Mich. Comp. Laws § 333.16274 with Cal. Health & Safety Code §§ 24185, 125300; N.J. Stat. § 26:2Z-2.

Finally, as *Glucksberg* recognized, 521 U.S. at 716, States have played a primary, dynamic – but not monolithic – role in addressing the legal, ethical, and medical issues involving end-of-life care and decisionmaking, cf. 42 U.S.C. § 1395cc(f). And they are playing an important role in responding to developments in pain medicine and in addressing documented problems of inappropriate undertreatment. See, *e.g.*, Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards* 31 J.L. Med. & Ethics 21, 23 (2003) ("In 1999, the Oregon Medical Board was the first in the nation to discipline a physician for failure to prescribe adequate pain relief medication").

D. Congress Did Not Intend The CSA To Standardize Medical Practice Nationwide

While the Attorney General insists that Congress should be "presumed" to have intended to standardize medical practice (with controlled substances) throughout the United States, the mere fact that the CSA is national in scope (and paramount in cases of "positive conflict" with State law) does not mean that Congress intended to broadly repudiate this beneficial State nonuniformity, see *Hillsborough County v. Automated Med.*

Labs., Inc., 471 U.S. 707, 719 (1985) (that "every subject that merits congressional legislation is, by definition, a subject of national concern [does not] * * * * mean * * * that every federal statute ousts all related state law"), and the CSA's textual indications are plainly "to the contrary," *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989).

As a matter of law and fact, the Act contemplates extensive variation in medical practice from State-to-State, and expressly references State law in both the key definitional section, 21 U.S.C. § 802(21), and the other provision the Attorney General invokes, *id.* § 823(f). Indeed, even the provisions cited as evidence of an intent to impose uniformity support the opposite conclusion. Thus, the 1984 amendment, while denying dispositive effect to State nonenforcement, contemplated that "deference" to State decision making would remain the norm, see p.13, *supra*. And while the Act's drug treatment provisions, see Pet.Br.33, *do* contemplate federally-formulated standards "of professional practice" in that one area, such an express and specific indication argues *against* treating silence in the rest of the Act as a broad mandate for national standards. Indeed, that specific authority involves a field of practice, dispensing scheduled drugs to drug-dependent patients, where the statute's core concerns are uniquely implicated – and even then, Congress took care to *limit* the Attorney General's role in *medical* decisionmaking, see p.6, *supra*.

Nor is there any tension between preserving State authority over medical practice and the trend away from the "locality rule" in medical malpractice lawsuits (Pet.Br.36). As explained above, malpractice law represents a single strand of State health care regulation – and, three decades after the CSA, there remains substantial diversity among States even in that field. Cf. *Rush Prudential*, 536 U.S. at 386 ("standards of reasonable medical care" are "quintessentially state-law" matters); *BMW N. America v. Gore*, 517 U.S. 559, 615 (1996) (Ginsburg, J., dissenting). And this development's significance is readily

overstated: many jurisdictions that no longer require injured plaintiffs to produce testimony of local *expert witnesses*, see M. Boumil & C. Elias, The Law of Medical Liability 30 (1995), continue to adhere to the "respected minority" doctrine – under which liability may *not* be imposed for noncompliance with the predominant view of proper practice, if the conduct is supported by any "competent medical authority, subscribed to by reputable, respectable and reasonable medical experts * * * in the field," *Tobash v. Jones*, 213 A.2d 588, 592 (Pa. 1965).

The Attorney General's other policy argument – that nonuniform standards of medical practice hamper prosecution of rogue doctors – is largely beside the point. For the reasons explained in Part I, even if it were clear that a single federal standard applied in cases charging doctors with "large scale drug trafficking," that would *not* establish the necessity or desirability of – let alone a congressional preference for – national uniformity as to the "legitimacy" of *every* medical practice that happened to involve controlled substances.

But even on that limited point, the case for national uniformity is not airtight. There does not seem much basis for concern that a jury would *acquit* a doctor, proved by the government to be selling drugs in contravention of widely accepted standards, based solely on the defendant's "own view," Pet.Br.35, of acceptable State practice. Cf. *Tesauro v. Perrige*, 650 A.2d 1079, 1082 (Pa. Super. Ct. 1994) (malpractice defendant bears burden of producing "adequate factual support for his claim that there are a considerable number of professionals who agree with the treatment"). By the same token, it is not obvious that a jury instructed as were those in the cases cited approvingly in the Attorney General's brief (Pet.Br.31) would *convict* a physician, in the rare instance where his conduct strictly complied with a "state statutory law governing the particular matter in question," *id.* at 35; in such an instance, it presumably would be hard for the Government to carry its burden of proving that the physician was not acting

"in good faith," see, *e.g.*, *United States v. Rosenberg*, 515 F.2d 190, 198 (9th Cir.1975), and there would be strong arguments against mounting a prosecution at all.[11]

Nor do the Court's recent decisions in "medical marijuana" cases support construing the CSA as enacting a national medical practice regulation – or a preemptive ban on assisted suicide. First, the legal issue presented here is nothing like the one decided in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) ("*OCBC*"), which held that a federal court's recognition of a "medical necessity" defense to a marijuana distribution charge would be precluded by the statutory determination that that the drug has *no* "accepted medical use." See *id.* at 483; cf. *Moore*, 423 U.S. at 142 (authority "under the CSA to dispense * * * Schedule I drugs * * * does not follow automatically from state registration as it does with respect to drugs in Schedules II through V, all of which have some accepted medical use"). *OCBC* recognized that a State law that purported to overrule the federal ban on distribution of marijuana would not only be in "positive conflict," 21 U.S.C. § 903, with that drug's placement on Schedule I, but also in tension with the statutory structure, which relies on centralized scheduling decisions, guided by

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[11]However rare such situations may be, Pet.Br.35, the exercise of power at issue here obviously *does* entail overruling "state statutory law governing the particular matter in question," *id.*

The question actually presented in *Moore* was whether a physician could ever be prosecuted under § 841 – not the standard for establishing guilt – but it is not at all "clear that Moore's conviction * * * was based on a uniform nationwide standard" (Pet. Br.31). As quoted in the opinion, the jury instruction directed that compliance "with *a* standard of medical practice generally recognized and accepted in the United States," 423 U.S. at 139 (emphasis added), would preclude conviction; and "the jury was instructed that Dr. Moore could not be convicted if he merely made 'an honest effort' to prescribe for detoxification in compliance with *an* accepted standard of medical practice," *id.* at 143 n.20 (emphasis added); see also *id.* at 126 ("The Government's position [was] that Dr. Moore's conduct was inconsistent with *all* accepted methods of treating addicts").

specific congressionally-identified factors, to determine whether – and subject to which controls – a substance may be distributed.[12]

Here, there is no "positive conflict" – or even implied conflict – between Oregon's exercise of its historic powers and *any* congressional determination, let alone any affront to the scheme of substance-based scheduling and controls that Congress enacted. This case does not involve enforcement of a federal prohibition "duplicative" of or "parallel" to a repealed State law, see Pet.Br.44: the Attorney General effectively claims power under the CSA *to create* a crime of "assisted-suicide [with a controlled substance]."[13]

III. Sustaining The Assertion of Authority Would Interfere With Proper Health Care

There are important public health reasons why even the powers Congress *did* confer on the Attorney General must be clearly and narrowly defined and sensitively exercised. As Congress, this Court, and others have often recognized, *patients*

[12]The suggestion (Pet.Br.29) that *OCBC* recognized the Attorney General's power to displace State laws to be *greater* than Congress's misreads the decision. Respondents in *OCBC* did *not* claim that the Attorney General had especially broad power under the CSA; their contention, rejected in the relevant opinion passage, was that because the mandatory § 812(b) criteria are binding only in an *administrative* scheduling, Congress's placement of marijuana on schedule I did not *literally* establish – as a lawful DEA classification *necessarily* would – that the drug had been determined to "lack accepted medical use."

[13]*Gonzales v. Raich*, 125 S. Ct. 2197 (2005), which addressed Congress's power *under the Constitution* to regulate intrastate marijuana possession for medical purposes, is of no more help to the Attorney General – and even less relevant. That decision proceeded from the premise that Congress had *in fact* prohibited Respondents' conduct by enacting the CSA, and then held that the decision to do so – supported by unquestioned power over interstate trafficking in marijuana and by findings that regulation of local activity was necessary to make the national prohibition effective – were within its Article I power. Cf. *New State Ice*, 285 U.S. at 311 (Brandeis, J., dissenting) (emphasizing value of State experimentation that poses no "risk to the rest of the country").

are ill-served when their doctors are deterred from practicing medicine in accordance with professional judgment – or from providing care at all. See *Moore*, 423 U.S. at 143 (noting presidential commission findings that "'fear of prosecution" leads "many physicians [to] * * * shun addicts as patients" or provide them inappropriate care); *Conant v. Walters*, 309 F.3d 629, 640 n.2 (9th Cir. 2002) (Kozinski, J., concurring) ("'[P]hysicians are particularly easily deterred by the threat of governmental investigation and/or sanction from engaging in conduct that is entirely lawful and medically appropriate'") (quoting expert report); cf. *Thompson*, 535 U.S. at 374 (recognizing benefits to patients of permitting physicians to prescribe compounded drugs and "off-label" uses).

The dangers of such deterrence are especially acute where controlled substances are involved. Not only does prescribing such medications subject the practitioner to far greater governmental scrutiny (heightening concerns about possible investigations and enforcement actions, see *infra*), but many individual physicians, like the rest of society, harbor inaccurate assumptions about the risks such drugs pose, see Oken, *Curing Healthcare Providers' Failure to Administer Opiods in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917, 1938 (2002); Morgan, *American Opiophobia: A Customary Underutilization of Opioid Analgesics*, in Controversies in Alcoholism and Substance Abuse (Stimmel, ed. 1986) at 171, and professional training historically did not treat their principal benefit – relieving patients' pain – as an important part of doctors' medical treatment responsibilities, see p. 10, *supra*.

For these reasons, the Directive and the construction of the Act on which it rests – which would grant the Attorney General broad and ill-defined power to investigate, discipline, and prosecute doctors for actions taken in good faith, in accord with professional judgment and State law, in situations where there is not even a suggestion of drug diversion – represent, from a public health perspective, a long step in the wrong direction.

A. The Directive Will Worsen Existing, Serious Inadequacies in End-of-Life Care

Both in Oregon and elsewhere, the Directive would negatively affect care in a field of medical practice – care for the terminally ill – in which legitimate concerns about drug diversion and addiction are at their nadir, and in which very serious inadequacies have already widely recognized.

As noted above, see p. 9, *supra*, the Directive's operation *in Oregon* would be troubling even on its own terms. Because it is limited to controlled substances, see § 811(b); Pet.Br.43, the Directive apparently would not stand in the way of Oregon physicians' pursuing the objected-to "aim[]" (Pet.Br.19), by means that the physician does not believe – and the Attorney General does not suggest – are more *medically* appropriate.[14]

The Directive's most serious adverse effects, however, would be in jurisdictions where traditional bans remain in effect. Notwithstanding the oblique assertion that increased enforcement activity outside Oregon is not "portend[ed]," the Directive plainly declares an intention to regulate end-of-life care throughout the Nation, *i.e.*, "regardless of whether state law authorizes or permits [assisting suicide] by practitioners or others and regardless of the condition of the person whose suicide is assisted," 66 Fed. Reg. at 56,608, threatening physicians who provide "illegitimate" assistance to terminally ill patients with "the penalties provided for violations of * * * law relating to controlled substances," 21 C.F.R. § 1306.04(a).

The impact of this unprecedented assertion of authority

[14]To the extent that the Directive is intended to dissuade *States* otherwise inclined to follow Oregon's course from doing so, its implications are also potentially perverse. In view of evidence that physician assistance occurs throughout the country, see Meier et al, *A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 N. Eng. J. Med. 1193 (2001), the Directive would give jurisdictions where the practice is tacitly accepted (but legally prohibited) strong incentive to remain beneath the Attorney General's "radar" – thereby denying patients the formal safeguards and public scrutiny that formal regimes like Oregon's provide.

must be understood in light of the already serious problem it would aggravate – inadequate palliative care for the terminally ill. Even absent the Directive, "[t]oo many dying people suffer from pain * * * that clinicians could * * * relieve with existing * * * therapies." Approaching Death at 2. The consensus view across a variety of disciplines is that undertreatment of pain is a pervasive public health problem. See Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. Med. & Ethics 332 (1998).[15]

As courts and researchers have recognized, this phenomenon is not primarily explained by a lack of available medications – or by "legal barriers to obtaining medication * * * to alleviate * * * suffering," *Glucksberg*, 521 U.S. at 736-37 (O'Connor, J., concurring), so much as by "reluctance of health care practitioners to use narcotic analgesics fully for therapeutic purposes." Martino, 26 J.L. Med. & Ethics at 333. As noted, see p. 25, *supra*, this reluctance is partly attributable to a professional culture that long neglected the importance of palliative care – and to doctors' own misconceptions about drug dependence – but it is significantly driven by apprehensions about the prospect of governmental investigation, legal sanctions, and the attendant professional stigma.[16]

[15]Studies have found that 41.2% of the 2.2 million residents of U.S. nursing homes have "persistent pain," Teno et al., *Persistent Pain in Nursing Home Residents*, 285 JAMA 2081 (2001); that large percentages of terminally ill patients spend their last days in moderate to severe pain, see *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591 (1995); that significant numbers of elderly cancer patients in nursing homes received no analgesics at all, Bernabei et al., *Management of Pain in Elderly Patients with Cancer*, 279 JAMA 1877 (1998); and that minority patients are at special risk of undertreatment, see Cleeland et al., *Pain Management in Minority Patients With Cancer*, 127 Annals Internal Med. 813 (1997); see also Von Roenn et al., *Physician Attitudes and Practices in Cancer Pain Management*, 119 Annals Internal Med. 121 (1993) (86% of physicians responded that the majority of cancer patients with pain were undermedicated).

[16]See, *e.g.*, Sabatino, *Removing Legal Obstacles to Effective Pain Management*, NAELA Q., Spring 2001, at 15, 19; Johnson, *Disciplinary*

Cases involving the terminally ill present special challenges, because drugs, if applied in certain dosages, can hasten death: "The threat of prosecution, the possibility of being labeled another Kevorkian, and the risk of losing prescribing or practice privileges are all strong incentives to say no, even in instances where the use of high doses of opioids is not only the legitimate, but also the most humane course of action," Martino, 26 J.L. Med. & Ethics at 337; see Haugen, *Pain Relief for the Dying: The Unwelcome Intervention of the Criminal Law*, 23 Wm. Mitchell L. Rev. 325 (1997); Kapp, *Treating Medical Charts Near the End of Life: How Legal Anxieties Inhibit Good Patient Deaths*, 28 U. Tol. L. Rev. 521 (1997).

Even though the Directive includes language professing recognition of the "important medical, ethical, and legal distinctions between intentionally causing a patient's death and providing sufficient dosages of pain medication necessary to eliminate or alleviate pain," 66 Fed. Reg. at 56,608, it can only aggravate these concerns. That language falls conspicuously short of recognizing a safe harbor (as some State laws have) for prescribing drugs that have the "double effect" of hastening death, see *Glucksberg*, 521 U.S. at 780 n.15 (Souter, J., concurring); indeed, nothing in the Directive indicates that the Attorney General would not investigate a physician who was in compliance with his or her State's provision. Even in those jurisdictions, physicians fearful of having their "intent" misread may refrain from administering (appropriately) high doses of pain medication to their terminally ill patients. See Groopman, *Separating Death From Agony*, N.Y. Times, Nov. 9, 2001, at A21 (describing as "medically impossible" to "dissociate intentionally ameliorating a dying patient's agony from intentionally shortening the time left to live").

Actions and Pain Relief: An Analysis of the Pain Relief Act, 24 J.L. Med. & Ethics 319, 320 (1996); Hill, *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287, 288 (1996).

The Directive would increase these deterrents vastly, by vesting medically untrained law enforcement agents with authority to ascertain a physician's "motive" in caring for a deceased patient; by raising the stakes of such investigations; and by heightening the danger that those making such inherently delicate judgments would apply conflicting standards.

B. The Authority Claimed, If Approved, Would Chill Legitimate Medical Practice And Distort the Process By Which Controversial Policy Questions Are Resolved

Sustaining the Attorney General's construction of the statute would not merely affect the subject matter of the *Directive*, but would enable a federal law enforcement presence in matters, far removed from the concerns that led to enactment of the CSA, that have always been for State resolution.

The construction of the statute advanced in this Court would also authorize actions against doctors for prescribing pain medication for patients who are *not* terminally ill, even when done in full, good faith compliance with "*state statutory law governing the particular matter in question*." Pet.Br.35 (emphasis added). As researchers have found, the tendency to undertreat severe pain of those *not* in the late stages of terminal disease is likely a more pervasive – and harder to solve – problem than is inadequate care at the end of life.[17]

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[17]Not only has end-of-life care received more focused policy attention, but many doctors' reluctance to prescribe potentially dependency-inducing medication is especially pronounced for patients with chronic pain, and the standards of proper care for management of such pain are less well-established. See Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective*, 24 J.L. Med. & Ethics 296 (1996); Davidson, *Pain and Opiophobia*, 40 Healthcare Forum J. 64 (1997); Hyman, *Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment*, 24 J.L. Med. & Ethics 338 (1996). See Federation of State Medical Boards of the United States, *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004) (recognizing undertreatment of pain to be a "serious public health problem" and citing doctors' "perception that prescribing adequate amounts of

Moreover, as explained above (pp. 10-11), the Attorney General's efforts to articulate a definition of "illegitimacy" not limited to "closed system" concerns would bring prescription of controlled substances in the course of *any* experimental or nontherapeutic medical procedure within the ambit of the CSA – with the Attorney General's available grounds for proceeding against a doctor (or overruling a State) not limited to reasons of drug control or even medical appropriateness.

It is no answer that the Attorney General might not attempt such further assertions of power. First, as just described, the threat of *conviction* is not needed to distort doctors' choices – in ways that disserve patients (and the Directive itself would hardly have been a foreseeable development from the vantage point of *Glucksberg* and *Quill*). But whether or not similar "interpretive rules" were ultimately to issue, the process for resolving difficult questions of policy and morality would be skewed, encouraging those who object to novel and controversial practices to bypass State-level (and even congressional) debate and ask the Attorney General to "stay experimentation" at the earliest possible stage (when a fully contrary "consensus" could most plausibly be claimed).

Such a regime would be inimical to the public health, and it is not what should happen in "a democratic society," *Glucksberg*, 521 U.S. at 735.

Conclusion

The judgment of the Court of Appeals should be affirmed.

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controlled substances will result in unnecessary scrutiny by regulatory authorities" as a contributing cause).

Respectfully submitted,

SEAN H. DONAHUE
2000 L. Street, Suite 808
Washington, DC 20036
(202) 466-2234

DAVID T. GOLDBERG
Counsel of Record
99 Hudson Street, 8th Fl.
New York, N.Y. 10013
(212) 334-8813

DANIEL N. ABRAHAMSON
Drug Policy Alliance,
Office of Legal Affairs
717 Washington St.
Oakland, CA 94607
(510) 208-7711

Counsel for *Amicus Curiae*

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR PROFESSORS OF LAW RICHARD BRIFFAULT, WILLIAM N. ESKRIDGE, JR., PHILIP P. FRICKEY, ELIZABETH GARRETT, JERRY L. MASHAW, EDWARD RUBIN, DAVID L. SHAPIRO, PETER L. STRAUSS, AND ERNEST A. YOUNG AS AMICI CURIAE SUPPORTING RESPONDENTS

DAVID W. OGDEN
Counsel of Record
PAUL R.Q. WOLFSON
DAVID S. MENDEL
DANIELLE SPINELLI
HEATHER ELLIOTT
NORA FREEMAN ENGSTROM
WILMER CUTLER PICKERING
HALE AND DORR LLP
2445 M Street, N.W.
Washington, DC 20037
(202) 663-6000

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF AMICI	1
INTRODUCTION AND SUMMARY OF ARGUMENT	3
ARGUMENT	5
I. THE STATUTORY AND REGULATORY SCHEME	5
II. THE DIRECTIVE IMPROPERLY PREEMPTS STATE LAW AND ALTERS THE TRADITIONAL FEDERAL-STATE BALANCE IN THE REGULATION OF MEDICAL PRACTICE	7
A. A Federal Statute Is Presumed Not To Preempt State Law Regulating The Practice Of Medicine	8
B. A Federal Statute Is Presumed Not To Alter The Federal-State Balance	10
C. The CSA Does Not Authorize The Attorney General To Set Uniform Standards Of Medical Practice For The States	12
III. THE RULE OF LENITY COUNSELS AGAINST THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA	19
IV. THE CSA SHOULD NOT BE READ TO PRECLUDE DEMOCRATIC DEBATE AND EXPLORATION OF DIFFERENT APPROACHES BY THE STATES ON THE QUESTION OF PHYSICIAN-ASSISTED SUICIDE	22
V. THE ATTORNEY GENERAL'S DIRECTIVE WARRANTS NO DEFERENCE	26
CONCLUSION	30

TABLE OF AUTHORITIES

CASES

Page(s)

Auer v. *Robbins*, 519 U.S. 452 (1997) 28
Babbitt v. *Sweet Home Chapter of Communities for a Greater Oregon*, 515 U.S. 687 (1995) 22
BFP v. *Resolution Trust Corp.*, 511 U.S. 531 (1994) 10, 11, 17
Chevron U.S.A. Inc. v. *Natural Rcsources Defense Council, Inc.*, 467 U.S. 837 (1984) 26
Christensen v. *Harris County*, 529 U.S. 576 (2000) 27
Cleveland v. *United States*, 531 U.S. 12 (2000) 21
Crandon v. *United States*, 494 U.S. 152 (1990) 20, 21
FDA v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) 29
Gibbons v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824) 8
Gonzales v. *Raich*, 125 S. Ct. 2195 (2005) 5
Gregory v. *Ashcroft*, 501 U.S. 452 (1991) 10, 11
Helvering v. *Stuart*, 317 U.S. 154 (1942) 17
Hillsborough County v. *Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985) 8
INS v. *Cardoza-Fonseca*, 480 U.S. 421 (1987) 28
Kent v. *Dulles*, 357 U.S. 116 (1958) 29
Leocal v. *Ashcroft*, 125 S. Ct. 377 (2004) 21
MCI Telecommunications Corp. v. *AT&T*, 512 U.S. 218 (1994) 26, 29
Martin v. *OSHRC*, 499 U.S. 144 (1991) 28
McNally v. *United States*, 483 U.S. 350 (1987) 20, 21
Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) 3, 8, 10
Mississippi Band of Choctaw Indians v. *Holyfield*, 490 U.S. 30 (1989) 17
New State Ice Co. v. *Liebmann*, 285 U.S. 262 (1932) 4, 24
Pegram v. *Herdrich*, 530 U.S. 211 (2000) 8
Rice v. *Santa Fe Elevator Corp.*, 331 U.S. 218 (1947) 8
Rogers v. *Tennessee*, 532 U.S. 451 (2001) 20
Rush Prudential HMO, Inc. v. *Moran*, 536 U.S. 355 (2002) 8

TABLE OF AUTHORITIES—Continued

Page(s)

Skidmore v. *Swift & Co.*, 323 U.S. 134 (1944) 26, 27
Solid Waste Agency of Northern Cook County v. *United States Army Corps of Engineers*, 531 U.S. 159 (2001) 10, 30
Thomas Jefferson University v. *Shalala*, 512 U.S. 504 (1994) 28, 29
Touby v. *United States*, 500 U.S. 160 (1991) 5, 6, 27
United States v. *Bass*, 404 U.S. 336 (1971) 10, 20, 21
United States v. *Kozminski*, 487 U.S. 931 (1988) 4, 19
United States v. *Mead Corp.*, 533 U.S. 218 (2001) 26, 27, 28
United States v. *Moore*, 423 U.S. 122 (1975) 15, 17, 18
United States v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) 17, 18
United States v. *Rosenberg*, 515 F.2d 190 (9th Cir. 1975) 18
United States v. *Thompson/Center Arms, Co.*, 504 U.S. 505 (1992) 21
Washington v. *Glucksberg*, 521 U.S. 702 (1997) ..... *passim*
Webb v. *United States*, 249 U.S. 96 (1919) 15
Whalen v. *United States*, 445 U.S. 684 (1980) 20
Whitman v. *American Trucking Associations*, 531 U.S. 457 (2001) 29

STATUTES

Controlled Substances Act
- 21 U.S.C. § 802 ..... 3, 6, 12, 15, 19
- 21 U.S.C. § 811 ..... 5, 6, 19, 28
- 21 U.S.C. § 812(b) 5, 18, 19
- 21 U.S.C. § 823(f) 5, 12, 13
- 21 U.S.C. § 829 ..... 3, 6
- 21 U.S.C. § 841(a) 3, 5
- 21 U.S.C. § 903 ..... 12, 18

42 U.S.C. § 290bb-2a 14
21 C.F.R. § 1306.04 6
66 Fed. Reg. 56,607 (Nov. 9, 2001) 7

TABLE OF AUTHORITIES—Continued

Page(s)

Oregon Death With Dignity Act
Or. Rev. Stat. § 127.805(1) 7
Or. Rev. Stat. § 127.815 7
Or. Rev. Stat. § 127.855 ..... 7, 25
Or. Rev. Stat. § 127.865 25
Or. Rev. Stat. § 127.885(1) 7
Pub. L. No. 91-513, 84 Stat. 1236 (1970) 13

LEGISLATIVE MATERIALS

H.R. Rep. No. 91-1444 (1970) 13, 14, 16
S. Rep. No. 98-225 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182 ..... 13, 14
H.R. 2260, 106th Cong. (1999) 16
H.R. 4006, 105th Cong. (1998) 16

OTHER AUTHORITIES

Letter from Attorney General Reno to Rep. Henry Hyde (June 5, 1998) 7
Manning, John F., *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 Colum. L. Rev. 612 (1996) 29
Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death With Dignity Act* (2005) 9, 25

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Amici curiae Richard Briffault, William N. Eskridge, Jr., Philip P. Frickey, Elizabeth Garrett, Jerry L. Mashaw, Edward Rubin, David L. Shapiro, Peter L. Strauss, and Ernest A. Young respectfully submit this brief supporting affirmance of the judgment below.[1]

INTEREST OF AMICI

Amici are law professors who teach and write from a range of perspectives on topics that include statutory interpretation, administrative law, legislative process, and federalism and who therefore have a professional interest in the proper application and development of law in these areas.

[1] No counsel for a party authored this brief in whole or in part, and no person or entity other than amici and their counsel made any monetary contribution toward the preparation or submission of this brief. Letters indicating the parties' consent to the filing of this brief have been submitted to the Clerk.

Richard Briffault, the Joseph P. Chamberlain Professor of Legislation and Director of the Legislative Drafting Research Fund at Columbia Law School, is the co-author of a leading casebook on state and local government law and has published widely on issues of federalism. William N. Eskridge, Jr., the John A. Garver Professor of Jurisprudence at Yale Law School, has written numerous scholarly articles on legislation and statutory interpretation and is the co-author, with Professors Frickey and Garrett, of the leading casebook and student treatise on legislation. Philip P. Frickey, the Richard W. Jennings Professor of Law at the University of California, Berkeley School of Law (Boalt Hall), has written extensively on statutory interpretation and the legislative process. Elizabeth Garrett, the Sydney M. Irmas Professor of Public Interest Law, Legal Ethics, Political Science, and Policy, Planning and Development at the University of Southern California, is the Director of the USC-Caltech Center for the Study of Law and Politics and has published widely in the areas of statutory interpretation and lawmaking. Jerry L. Mashaw, the Sterling Professor of Law at Yale Law School, is the author of numerous scholarly articles on administrative law and legislation and has co-authored a leading casebook on administrative law. Edward Rubin, the Dean and John Wade-Kent Syverud Professor of Law at Vanderbilt University Law School, has written extensively in the fields of administrative law and statutory interpretation. David L. Shapiro, the William Nelson Cromwell Professor of Law at Harvard Law School, has published widely in the areas of federalism, administrative law, and statutory interpretation. Peter L. Strauss, the Betts Professor of Law at Columbia Law School, is the co-author of a leading administrative law casebook and the author of numerous scholarly articles on administrative law and statutory interpretation. Ernest A. Young, the Judge Benjamin Harrison Powell Professor in Law at the University of Texas School of Law, has written extensively on issues of federalism and constitutional and statutory interpretation.

While this case implicates profound and difficult questions regarding end-of-life care, it is at bottom a case about determining congressional intent: this Court must determine whether the Controlled Substances Act (CSA) makes it a crime, or grants the Attorney General the power to make it a crime, for physicians to prescribe controlled substances as authorized by the Oregon Death With Dignity Act (ODWDA). Amici respectfully seek to provide the Court with a discussion of principles of statutory construction and administrative law that bear on that question.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case undoubtedly raises important issues relating to the ability of terminally ill patients to obtain the assistance of physicians in ending their lives. What should not be obscured, however, is that this case fundamentally presents a question of statutory interpretation. The threshold—and, in our view, dispositive—question before this Court is whether the Attorney General's Directive is a legitimate reading of the CSA's requirement that doctors prescribing controlled substances must act "in the course of professional practice." 21 U.S.C. § 802(21); *see id.* §§ 829, 841(a).

Two fundamental principles of statutory construction are relevant to that inquiry. *First*, the Directive's reading of the CSA contravenes the presumption that, absent a clear statement, a federal statute will not be read to preempt state law or significantly to alter the federal-state balance. Here, the Directive effectively precludes Oregon residents from exercising the option made available to them by Oregon law, preempting Oregon's choice expressly to permit the prescription of controlled substances for that purpose. And it does so by intruding into an area—the regulation of medical practice—that is "primarily, and historically, a matter of local concern." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996) (citation omitted). But the CSA—which was enacted for the very different purpose of addressing illicit drug trafficking and abuse—does not set uniform standards of medical practice for the States or authorize the Attorney General to do so. To the contrary, the CSA expressly provides that

it does not preempt state law unless that law presents a positive conflict with its terms; the relevant provisions of the CSA expressly turn in part on state law; and the CSA grants the Attorney General no authority to make scientific or medical decisions. The text, structure, and purpose of the CSA make plain that Congress did not intend to displace the States' traditional authority to regulate medical practice within their borders.

Second, the Attorney General's aggressive reading of the CSA criminalizes conduct that the CSA does not plainly prohibit. It is a "time-honored interpretive guideline," however, "that uncertainty concerning the ambit of criminal statutes should be resolved in favor of lenity." *United States* v. *Kozminski*, 487 U.S. 931, 952 (1988). The rule of lenity ensures that Congress—the most democratically accountable branch—has carefully considered whether to create a federal crime and has made a conscious judgment to do so. Because the CSA does not clearly make state-authorized physician-assisted suicide a crime or give the Attorney General the power to do so, the rule of lenity strongly counsels against the Directive's interpretation.

Both of these canons ultimately stem from respect for the democratic process in our federal system and are intended to ensure that difficult and important social questions—particularly those that affect vital state interests—are resolved through that process. They are thus particularly relevant to this case, in which Oregon voters have decided to permit their State to "serve as a laboratory," implementing the "novel social . . . experiment[]" of regulated and controlled physician-assisted suicide "without risk to the rest of the country." *New State Ice Co.* v. *Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). As this Court has observed, "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide." *Washington* v. *Glucksberg*, 521 U.S. 702, 735 (1997). The Directive would bring that "earnest and profound debate" to an end. Because there is no evidence Congress intended

that result, this Court should reject the Directive, permitting the people of the States to continue democratic debate and exploration of different approaches to end-of-life care.

Finally, because the Directive is not a permissible reading of the CSA, this Court need not reach the Attorney General's claim that the Directive is entitled to deference. Were it to reach that question, however, basic tenets of administrative law mandate that the Directive's novel and expansive construction of the CSA—an informal interpretive rule issued without notice and comment and purporting to resolve a morally and politically fraught question on which the Attorney General has no expertise—should receive no deference. The Attorney General's unpersuasive attempt to overreach his authority under the CSA should be rejected.

ARGUMENT

I. THE STATUTORY AND REGULATORY SCHEME

The CSA, enacted in 1970, makes it a crime to possess, distribute, or dispense a controlled substance "[e]xcept as authorized" by the statute. 21 U.S.C. § 841(a)(1). As this Court recently explained: "The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Gonzales* v. *Raich*, 125 S. Ct. 2195, 2203 (2005) (footnotes omitted).

To that end, the CSA classifies controlled substances into five "schedules." 21 U.S.C. § 812. Substances with "no currently accepted medical use in treatment in the United States" are placed in Schedule I, *id.* § 812(b)(1)(B), and may be dispensed only for extremely limited research purposes, *see id.* § 823(f). By contrast, substances with "a currently accepted medical use in treatment in the United States" are placed in Schedules II-V, *id.* § 812(b)(2)-(5), and may be dispensed by physicians to patients as authorized by the CSA.

Under the CSA, the Attorney General may decide that a substance should be controlled and place it on a particular schedule. *See id.* § 811(a); *Touby* v. *United States*, 500 U.S.

160, 162-163 (1991). Before doing so, however, he must obtain a scientific and medical evaluation of the drug from the Secretary of Health and Human Services, and he may not control the drug if the Secretary recommends against it. 21 U.S.C. § 811(b). Indeed, the Secretary's recommendations are "binding" as to all "scientific and medical matters." *Id.* The Attorney General has no authority to make medical and scientific determinations relevant to scheduling decisions.[2]

The CSA provides that substances on Schedules II-V may be dispensed by practitioners who are federally registered to do so, *see id.* § 823(f), and are acting "in the course of professional practice," *id.* § 802(21) (defining "practitioner" as one who acts "in the course of professional practice"); *see id.* § 829 (providing that "practitioners" may prescribe or dispense controlled substances).

In 1971, through notice-and-comment rulemaking, the Attorney General promulgated a regulation implementing the CSA's "course of professional practice" requirement. The regulation provides: "A prescription for a controlled substance, to be effective, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. A prescription not "issued . . . in the usual course of . . . professional treatment" is invalid, and writing such a prescription is a crime. *Id.*[3]

In 1994, by ballot initiative, the people of Oregon adopted the ODWDA, which provides that "[a]n adult who is capable, is a resident of Oregon, and has been determined [by two physicians] to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose

[2] The Attorney General must also consider eight specified factors and comply with the notice-and-comment provisions of the Administrative Procedure Act before adding a drug to a schedule. *See* 21 U.S.C. § 811(a), (c); *Touby*, 500 U.S. at 162-163.

[3] Amici do not question the validity of the 1971 regulation.

of ending his or her life in a humane and dignified manner." Or. Rev. Stat. § 127.805(1). The statute expressly authorizes physicians to prescribe such medication if its requirements are met, *see id.* § 127.815, and provides that physicians who do so shall not "be subject to civil or criminal liability or professional disciplinary action," *id.* § 127.885(1).

After passage of the ODWDA, various persons, including then-Senator John Ashcroft, sought an opinion from then-Attorney General Janet Reno as to whether a doctor who prescribed controlled substances under the ODWDA would violate the CSA. After considering the views of parties on both sides of the question, Attorney General Reno concluded: "There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice . . . . [T]he CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Letter from Attorney General Reno to Rep. Henry Hyde at 4-5 (June 5, 1998).

In 2001, Ashcroft, now himself the Attorney General, reversed course by issuing the Directive, an informal interpretive rule issued without notice and comment or any consultation with Oregon and other interested parties. The Directive provides that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04" and therefore "that prescribing, dispensing, or administering federally controlled substances to assist suicide violates" the CSA, "regardless of whether state law authorizes or permits such conduct." 66 Fed. Reg. 56,607 (Nov. 9, 2001).

II. THE DIRECTIVE IMPROPERLY PREEMPTS STATE LAW AND ALTERS THE TRADITIONAL FEDERAL-STATE BALANCE IN THE REGULATION OF MEDICAL PRACTICE

It is a well-settled principle—deriving from the most basic aspects of our federal system—that if Congress intends to preempt state law or otherwise displace state authority in an arena traditionally regulated by the States, it

will say so in plain terms. No such plain statement appears in the CSA. Rather, the text and structure of the statute make clear that Congress intended to leave the substantive regulation of the practice of medicine—including the resolution of hotly debated questions of medical ethics, such as appropriate measures for end-of-life care—where it has always primarily been, with the States. The Directive's contrary interpretation therefore cannot be sustained.

A. A Federal Statute Is Presumed Not To Preempt State Law Regulating The Practice Of Medicine

The States' primary authority to regulate the practice of medicine has been well-settled since the early days of the Republic. *See Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824) (the police powers of the States include "[i]nspection laws, quarantine laws, [and] health laws of every description"). This Court has often reiterated that "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985); *see also Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996). Indeed, establishing "standards of reasonable medical care" is a "quintessentially state-law" function. *Rush Prudential HMO, Inc.* v. *Moran*, 536 U.S. 355, 387 (2002).

This Court has often held that where "Congress [has] legislated . . . in a field which the States have traditionally occupied . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). "[I]n the field of health care, a subject of traditional state regulation, there is no . . . preemption without clear manifestation of congressional purpose." *Pegram* v. *Herdrich*, 530 U.S. 211, 237 (2000); *see also, e.g., Medtronic*, 518 U.S. at 485.

The Attorney General's Directive would preempt central provisions of the ODWDA by making it a crime for doctors to prescribe controlled substances in the manner expressly authorized by the Oregon law. The Attorney General argues (Br. 44) that no preemption occurs because Oregon physicians remain free to "dispense substances other than those regulated under the CSA to hasten their patients' deaths." But every prescription written thus far under the ODWDA has been for barbiturates—Schedule II controlled substances under the CSA.[4] The Attorney General points to no way in which Oregon physicians could safely and effectively accomplish the purposes of the ODWDA without prescribing federally controlled substances. In any event, even if the Directive might leave intact some highly theoretical applications of the ODWDA, it precludes most of the statute's applications. The Attorney General's argument is therefore at best a quibble over the *scope*, not the *fact*, of preemption.

The Attorney General also contends (Br. 43) that the Directive does not preempt Oregon law because the ODWDA is still valid insofar as it exempts physicians from *state* prosecution. But this wholly misapprehends the effect of the Directive. The ODWDA expressly authorizes doctors to prescribe medications, including federally controlled substances, in accordance with its terms. Under the Supremacy Clause, however, Oregon *cannot* authorize Oregon doctors to take action that is prohibited by federal law. Thus, if the Directive validly stated federal law, its prohibition would preempt the contrary provisions of the ODWDA.

The Attorney General's contention that "States are not free to displace the federal-law duty to comply with the CSA" (Br. 44) merely begs the question. Clearly Oregon law cannot "preempt" the CSA. But the question here is the *meaning* of the CSA—and that meaning must be determined against the backdrop principle that Congress does not lightly intrude into areas traditionally regulated by the States. Nor can the Attorney General evade this principle

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[4] *See* Oregon Dep't of Human Services, *Seventh Annual Report on Oregon's Death With Dignity Act* 14 (2005).

with the claim that the Directive merely "frustrates the purposes of Oregon's voter initiative" (Br. 43). Respect for the States' sovereignty, and their primary authority over the regulation of medicine within their borders, requires that federal statutes be interpreted so as *not* to frustrate state law, absent a clear indication that Congress so intended. As shown below, *see infra* Part II.C, no such indication appears in the CSA.

B. A Federal Statute Is Presumed Not To Alter The Federal-State Balance

The basic interpretive principle that statutes are construed to respect the States' status as "independent sovereigns in our federal system," *Medtronic*, 518 U.S. at 485, extends beyond the context of preemption. Although "Congress may legislate in areas traditionally regulated by the States," this is "a power that we must assume Congress does not exercise lightly." *Gregory* v. *Ashcroft*, 501 U.S. 452, 460 (1991). Thus, "unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance" by making law in an area historically reserved to the States. *United States* v. *Bass*, 404 U.S. 336, 349 (1971); *see also, e.g., Solid Waste Agency of N. Cook County* v. *United States Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001); *BFP* v. *Resolution Trust Corp.*, 511 U.S. 531, 544 (1994). This clear statement rule "assures that [Congress] has in fact faced, and intended to bring into issue, the critical issues involved" when it legislates in an area traditionally reserved to the States. *Bass*, 404 U.S. at 349.

The Attorney General mistakenly contends (Br. 38-39) that the Directive does not implicate this rule because it does not reach to the core of state sovereignty. Although *Gregory* v. *Ashcroft* applied the rule to avoid federal interference with state law establishing the qualifications of state judges, *see* 501 U.S. at 460, the rule's application is not limited to such circumstances. Rather, as both *Bass* and *BFP* make clear, the rule applies whenever a federal statute "would mark a major inroad into a domain traditionally left to the States." *Bass*, 404 U.S. at 339 (applying rule to hold

that federal criminal statute did not criminalize conduct already made a crime by state law). "Federal statutes impinging upon important state interests 'cannot . . . be construed without regard to the implications of our dual system of government.'" *BFP*, 511 U.S. at 544 (citation omitted). Congress may override state law in an area traditionally regulated by the States when it does so unambiguously; "[b]ut where the intent to override is doubtful, our federal system demands deference to long-established traditions of state regulation." *Id.* at 546.

The question in *BFP* was the meaning of the phrase "reasonably equivalent value" in the Bankruptcy Code's fraudulent transfer provisions. This Court held that, when property is sold at a foreclosure sale conducted in accordance with state law, whatever price is thereby obtained is "reasonably equivalent value." *See BFP*, 511 U.S. at 545. The Court reasoned that interpreting "reasonably equivalent value," as the court of appeals had done, to "specify a federal 'reasonable' foreclosure-sale price," *id.* at 540, would cast a cloud on the title of much foreclosed property, frustrating state law in an area historically the province of the States. *See id.* at 544. Because the statute evinced no "clear and manifest" intent "[t]o displace traditional state regulation in such a manner," it would not be read to do so. *Id.*

This case presents very similar concerns. The Attorney General's interpretation of the CSA directly impinges on an important state interest in an area traditionally regulated by the States. The purpose of the clear statement rule is to preserve a "federalist structure of joint sovereigns . . . that will be more sensitive to the diverse needs of a heterogeneous society" and that "increases opportunity for citizen involvement in democratic processes; [and] allows for more innovation and experimentation in government." *Gregory*, 501 U.S. at 458. That purpose is plainly implicated here. The Directive not only intrudes upon a realm historically the province of the States, but goes much further—it purports to resolve complex moral questions regarding end-of-life care, questions that are the subject of "an earnest and pro-

found debate" among the people of the States. *Washington* v. *Glucksberg*, 521 U.S. 702, 735 (1997). Before adopting such an interpretation of a statute whose primary purpose was to address quite different questions, it is appropriate to take great care to ensure that Congress intended that result.

C. The CSA Does Not Authorize The Attorney General To Set Uniform Standards Of Medical Practice For The States

1. The CSA contains no indication—clear or otherwise—that Congress intended to grant the Attorney General the power to set uniform federal standards of medical practice for the States. To the contrary, the CSA expressly states that it should *not* be construed to override state law unless the conflict between the text of the CSA and state law is plain. *See* 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together."). There is no such positive conflict here.

Indeed, from the beginning, the CSA has looked to state law to determine which persons are "practitioners" acting "in the course of professional practice" and are thus eligible for federal registration to dispense controlled substances. The very definition of "practitioner" under the CSA turns in part on state law, providing that a "practitioner" includes "a physician . . . licensed . . . by the United States *or the jurisdiction in which he practices* . . . to . . . dispense . . . a controlled substance *in the course of professional practice*." 21 U.S.C. § 802(21) (emphasis added). That provision clearly contemplates that state law will inform the contours of "the course of professional practice" for purposes of the CSA.

The CSA's registration provisions also expressly recognize the primacy of state law in determining the circumstances under which controlled substances may properly be dispensed. The statute provides that "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances in Schedule II, III, IV, or V, *if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.*" *Id.* § 823(f) (emphasis added). Under the CSA as originally enacted, registration was "a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law." H.R. Rep. No. 91-1444, pt. 1, at 23 (1970). The Attorney General was authorized to revoke or suspend a registration only if the registrant had materially falsified his application, had been convicted of a felony relating to controlled substances, or "had his State license or registration suspended, revoked, or denied by competent State authority." Pub. L. No. 91-513, § 304(a), 84 Stat. 1236, 1255 (1970).

In 1984, Congress amended the CSA's registration provisions in order to address "the problem of diversion of dangerous drugs" into the hands of drug abusers, against which "many States [had been] unable to take effective or prompt action."[5] As amended, the statute continues to provide that practitioners licensed by the State in which they practice are presumptively entitled to registration. *See* 21 U.S.C. § 823(f). The Attorney General may deny, suspend, or revoke a registration of a state-licensed practitioner if doing so is in "the public interest." *Id.* In determining the "public interest," however, the Attorney General must consider five factors, the first of which is "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority." *Id.* § 823(f)(1).[6] The statute itself thus

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[5] S. Rep. No. 98-225, at 266 (1983); *see also id.* at 266-267 (citing, as a key reason for the amendment, "delays in obtaining conviction" under state law of doctors who have "abused their authority to dispense controlled substances").

[6] Two other factors also turn in part on state law—"[t]he applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances," *id.* § 823(f)(3), and "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," *id.* § 823(f)(4).

makes clear that the Attorney General is still expected to defer to the views of state licensing authorities, and that Congress did not intend to override the States' primary authority to regulate medical practice.[7] Congress's objective in amending the statute was much narrower: to ensure that doctors acting as drug dealers would not retain their federal registration merely because state authorities failed adequately to enforce state law.

The statute makes clear that, had Congress intended to impose a uniform federal standard for medical practice, it knew how to do so. The CSA does expressly contemplate uniform federal standards in one narrow area: the treatment of narcotics addiction. *See* 42 U.S.C. § 290bb-2a ("The Secretary of Health and Human Services, after consultation with the Attorney General . . . shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts . . . ."). Notably, however, the authority to devise this standard was given to the Secretary, *not* the Attorney General, whom Congress has consistently declined to entrust with medical decisions. *See id.*[8] Congress's explicit decision to permit the Secretary to create uniform federal standards in this narrow area, combined with its more general reluctance to displace state regulation of medical practice, show that Congress did not empower the Attorney General to override state regulation of medical practice in other areas.

[7] The legislative history confirms what the text makes plain: "the amendment would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applications." S. Rep. No. 98-225, at 267.

[8] The Attorney General's reliance on these provisions (Br. 32-33) is accordingly misplaced; they demonstrate not that Congress intended to give the Attorney General the power to set uniform standards of medical practice for the States in all contexts, but rather that it intended to give the *Secretary* the power to do so in one specific narrow context. *See* H.R. Rep. No. 91-1444, at 15 (expressing "concern[] about the appropriateness of having Federal officials determine the appropriate method of the practice of medicine," but opining that it was necessary to set uniform federal standards in that specific area in order to address doctors' unwillingness to accept drug addicts as patients).

2. In the face of this powerful evidence that Congress did not intend to give the Attorney General the power to displace the States' long-standing regulatory authority over the practice of medicine, the Attorney General first argues (Br. 18-19) that the statute's "course of professional practice" requirement, 21 U.S.C. § 802(21), itself clearly prohibits the prescription of controlled substances for the purpose of physician-assisted suicide. But that phrase, on its face, is certainly broad enough to encompass any medical practice expressly authorized by state law. Indeed, this Court has interpreted the "course of professional practice" standard to mean only that, when prescribing controlled substances, a doctor must be acting in the service of what he believes to be the good of his patients, rather than some other goal, such as personal gain. That is, a doctor must be acting *as a doctor* and not as a drug dealer. Thus, in *United States* v. *Moore*, this Court held that a doctor violated the CSA by prescribing controlled substances "not for legitimate purposes, but 'primarily for the profits to be derived therefrom,'" 423 U.S. 122, 135 (1975), and thus "act[ing] as a large-scale 'pusher' not as a physician," *id.* at 143.[9]

Lacking any more persuasive evidence in the text of the statute, the Attorney General falls back on the argument (Br. 18-19) that dictionary definitions of the word "medicine" exclude physician-assisted suicide as a "legitimate medical purpose"—the phrase employed by the regulation. But, as

[9] Similarly, this Court's decision in *Webb* v. *United States*, 249 U.S. 96 (1919)—relied on by the Attorney General (Br. 19)—held that a doctor who sold morphine to addicts solely to assist them in satisfying their addiction was not acting in the course of professional practice within the meaning of the Harrison Act, the predecessor to the CSA. *See* 249 U.S. at 97. Neither case remotely suggests that the CSA intended to go beyond criminalizing the illicit distribution of drugs for profit to supersede the States' authority to define the practice of medicine.

the Attorney General himself acknowledges (Br. 17 n.6), the regulation's "legitimate medical purpose" standard merely restates the statute's "course of professional practice" requirement. It does not—and indeed could not—criminalize conduct not reached by the terms of the CSA itself.

In any event, the Attorney General's wooden recitation of dictionary definitions does not support his view that the CSA empowers him to make physician-assisted suicide a crime. The definitions of "medicine" that he cites—which include "alleviation" of "disease" (Br. 19)—are not inconsistent with the position that the end-of-life care authorized by the Oregon statute is a legitimate medical practice. More importantly, the boundaries of legitimate medical practice raise scientific and moral questions far too complex to be resolved by invoking the dictionary. "[T]he good physician is not just a mechanic of the human body whose services have no bearing on a person's moral choices, but one who does more than treat symptoms, one who ministers to the patient.... This idea of the physician as serving the whole person is a source of the high value traditionally placed on the medical relationship." *Glucksberg*, 521 U.S. at 779 (Souter, J., concurring in the judgment). Nothing in either the CSA or the regulation suggests otherwise, or intimates that Oregon may not permit doctors, in the course of their professional practice, to assist a terminally ill person to control the circumstances of his death.[10]

[10] The Attorney General's contention (Br. 19-20) that the CSA's legislative history reveals an intention to prohibit the use of controlled substances in connection with physician-assisted suicide is equally misguided. The only reference to suicide in the House and Senate Reports occurs in the context of a discussion concerning intentional and accidental overdoses resulting from use *contrary* to or without professional advice, H.R. Rep. No. 91-1444, at 35 (1970), not in accordance with it. Notably, in 1998 and again in 1999, Congress rejected legislation that would have expressly extended the CSA to physician-assisted suicide. H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998"); H.R. 2260, 106th Cong. (1999) ("Pain Relief Promotion Act of 1999").

3. The Attorney General next contends that the CSA must establish uniform standards for medical practice because "'in the absence of a plain indication to the contrary, ... Congress when it enacts a statute is not making the application of the federal act dependent on state law.'" Pet. Br. 25 (quoting *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989)). But this "general assumption," *Holyfield*, 490 U.S. at 43, is simply inapplicable here, because the CSA contains several "plain indication[s] to the contrary": Congress defined "practitioner" in part by reference to state law; required that the Attorney General consider state law in registering practitioners to dispense controlled substances; and chose explicitly to adopt a uniform federal standard concerning the treatment of drug addicts, while declining to do so for any other area of medical practice.[11] Congress clearly contemplated that the application of the CSA in regulating physicians would vary from state to state.

Neither *United States* v. *Moore* nor *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (discussed at Pet. Br. 28-32), supports a contrary conclusion. *Moore* confirmed that the CSA "limit[s] a registered physician's dispensing authority to the course of his 'professional practice.'" 423 U.S. at 140. Because Moore "concede[d] in his brief that he did not observe generally accepted medical practices," *id.* at 126, however, this Court had no occasion to consider whether the CSA generally was intended to displace state determinations of what constitutes "professional

[11] It is not rare for Congress to make the application of a federal statute dependent on state law, even without saying so expressly. *See, e.g.*, *BFP*, 511 U.S. at 544 (holding that the term "reasonably equivalent value" in the Bankruptcy Code's fraudulent transfer provisions implicitly incorporates state-law standards in the context of foreclosure sales); *Helvering* v. *Stuart*, 317 U.S. 154, 161-162 (1942) (holding that the "necessary implication" of federal tax statute is that conditions for taxing trust assets depend on state property law, because "[t]he power to transfer or distribute assets of a trust is essentially a matter of local law").

practice."[12] Indeed, as discussed above, *Moore* held that the application of the CSA "turn[s] on whether the 'transaction' falls within or without legitimate channels" of distribution—that is, whether the doctor was "act[ing] as a . . . 'pusher' not as a physician." *Id.* at 135, 143. *Moore* provides no support for the Attorney General's notion that the CSA sets substantive standards for medical practice where, as here, a doctor is *not* acting as a drug dealer.[13]

Oakland Cannabis is similarly unhelpful to the Attorney General. There, this Court held that, because marijuana is a Schedule I drug with "'no currently accepted medical use,'" 532 U.S. at 491 (quoting 21 U.S.C. § 812(b)(1)(B)), "medical necessity is not a defense" to the CSA's prohibition of its manufacture and distribution, *id.* at 494. In other words, *Oakland Cannabis* involved a state law that—unlike the ODWDA—*did* create a "positive conflict," 21 U.S.C. § 903, with the express terms of the CSA.

The Attorney General argues (Br. 29-30) that because he could "reclassify the Schedule II substances typically used by Oregon physicians to assist suicide to Schedule I if the medical and scientific evidence warranted," he must also have the authority to override the States' judgment regarding which uses of Schedule II substances are medically acceptable. This greater-power-includes-the-lesser logic is flawed, because there is an important difference in the nature of federal authority with respect to Schedule I drugs

[12] Moreover, *Moore* dealt with the distribution of methadone ostensibly to treat heroin addicts, *id.* at 125-127—the one context in which the CSA does seek to establish uniform federal standards for medical practice.

[13] The court of appeals decisions on which the Attorney General relies (Br. 32) similarly involved doctors "not acting in good faith as . . . doctor[s], but simply pushing pills" for profit. *United States* v. *Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975). Although *Rosenberg* rejected the defendant's claim that the federal government could not constitutionally regulate medical practice and thus could not convict him absent a prior state conviction, neither *Rosenberg* nor any of the other decisions suggests that a doctor could act outside "the course of professional practice" by engaging in a medical practice expressly authorized by state law.

and drugs on other schedules. A drug on Schedule I has been federally determined to have "no currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B), and thus no state has the power to create or approve such a use (as this Court held in *Oakland Cannabis*). Drugs on other schedules, however, have accepted medical uses and may be dispensed to patients by practitioners acting "in the course of professional practice." *Id.* § 802(21). As discussed above, the CSA contemplates that the Attorney General will defer to the States' primary authority to regulate the "professional practice" of medicine.

Indeed, even with respect to classification, the CSA expressly refuses to grant the Attorney General the authority to make medical and scientific determinations—instead giving that power solely to the Secretary of Health and Human Services. *See id.* § 811(b). This provision reflects Congress's common-sense recognition that, as a law enforcement official, the Attorney General has no scientific or medical expertise and thus should not be given the power to decide such questions. The Attorney General's construction of the CSA—under which the statute expressly precludes him from making medical determinations relating to classification, yet implicitly grants him the power to set standards of medical practice for the States—is simply implausible.

III. THE RULE OF LENITY COUNSELS AGAINST THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA

Under the Attorney General's novel and aggressive interpretation of the CSA, a doctor commits a crime—and is subject to criminal penalties, as well as the loss of federal registration—when he prescribes controlled substances for a medical purpose expressly authorized by Oregon law. As demonstrated above, the CSA does not permit that construction. Even if the CSA were unclear on this point, however, it is a "time-honored interpretive guideline that uncertainty concerning the ambit of criminal statutes should be resolved in favor of lenity." *United States* v. *Kozminski*, 487 U.S. 931, 952 (1988). When confronted with "two rational readings of a criminal statute, one harsher than the other,

we are to choose the harsher only when Congress has spoken in clear and definite language." *McNally* v. *United States*, 483 U.S. 350, 359-360 (1987); *see also, e.g.*, *Crandon* v. *United States*, 494 U.S. 152, 158 (1990).

The rule of lenity—an application of the fundamental principle *nulla poena sine lege*[14]—is a means of effectuating Congress's intent. It presumes that, if Congress has not clearly stated its decision to make a particular act a crime, it likely has not carefully weighed the considerations that would inform that decision. "[B]ecause of the seriousness of criminal penalties, and because criminal punishment usually represents the moral condemnation of the community, legislatures"—and not courts or prosecutors—"should define criminal activity." *Bass*, 404 U.S. at 348; *see also, e.g.*, *Whalen* v. *United States*, 445 U.S. 684, 689 (1980) ("[W]ithin our federal constitutional framework . . . the power to define criminal offenses . . . resides wholly with the Congress."). By requiring Congress to speak "in clear and definite language," *McNally*, 483 U.S. at 360, the rule of lenity ensures that Congress has in fact made a considered decision to make the conduct at issue a crime. As shown above, *see supra* Part II, the CSA contains no language authorizing the Attorney General to regulate medical practice, much less to make this particular instance of medical practice a federal crime. The Directive thus improperly arrogates to the chief federal prosecutor—contrary to the most basic principles governing criminal law—the power to define a crime.

The rule of lenity plays a particularly vital role where, as here, the government's proposed expansive interpretation of a federal criminal statute would intrude on areas traditionally regulated by the States. In such a situation, it is even less likely that Congress would have intended to create a crime by implication. Thus, in *Bass*, this Court held that,

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[14] *See, e.g.*, *Rogers* v. *Tennessee*, 532 U.S. 451, 467-468 (2001) (Scalia, J., dissenting) (noting that the maxim "'dates from the ancient Greeks and has been described as one of the most 'widely held value-judgment[s] in the entire history of human thought'" (citation omitted)).

where the government's interpretation of a criminal statute would "significantly change[] the federal-state balance," it is especially appropriate to require that Congress have spoken clearly before adopting that interpretation. *Bass*, 404 U.S. at 349. Similarly, in *Cleveland* v. *United States*, the Court adopted a narrow reading of the federal mail fraud statute because a broader interpretation would "subject to federal mail fraud prosecution a wide range of conduct traditionally regulated by state and local authorities." 531 U.S. 12, 24 (2000). And in *McNally*, the Court applied the rule of lenity to construe the federal mail fraud statute not to reach a scheme by state officials to deprive victims of an intangible right to honest government, because that reading would intrude on a realm that is primarily the province of the States. *See* 483 U.S. at 360.

The rule of lenity applies here even though the Attorney General may choose not to pursue criminal prosecution. *See, e.g.*, *Leocal* v. *Ashcroft*, 125 S. Ct. 377 (2004). In *Leocal*, this Court held that it was "constrained to interpret any ambiguity in the statute in [the defendant's] favor" because, even though the statute was not being used in a criminal context, "it has both criminal and noncriminal applications. Because we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context, the rule of lenity applies." *Id.* at 384 n.8; *see also Crandon*, 494 U.S. at 158 (even for a civil penalty "set forth in a criminal statute, it is appropriate to apply the rule of lenity in resolving any ambiguity in the ambit of the statute's coverage"); *United States* v. *Thompson/Center Arms Co.*, 504 U.S. 505, 517-518 (1992) (plurality opinion) (applying rule of lenity to a tax statute construed in a civil setting because the statute also created criminal liability); *id.* at 519 (Scalia, J., concurring in the judgment) (same).

Because the Attorney General's interpretation of the CSA creates criminal liability where there is no evidence that Congress intended to make the conduct at issue a crime

or to grant the Attorney General the power to do so, the rule of lenity counsels that it should be rejected.[15]

IV. THE CSA SHOULD NOT BE READ TO PRECLUDE DEMOCRATIC DEBATE AND EXPLORATION OF DIFFERENT APPROACHES BY THE STATES ON THE QUESTION OF PHYSICIAN-ASSISTED SUICIDE

Both the presumption that Congress will not casually intrude into an area traditionally the province of the States and the rule of lenity ultimately derive from respect for the democratic process in our Federal system. Those canons give effect to the principle that certain questions are particularly inappropriate for resolution by courts and prosecutors, and that it is thus particularly critical to ensure that Congress, as the most democratically accountable branch, has carefully considered and clearly resolved them.

That is especially true in this case. The Directive purports to resolve the hotly disputed scientific, medical, and, at bottom, moral question whether physician-assisted suicide can ever be a part of legitimate medical practice. Less than ten years ago, in *Washington* v. *Glucksberg*, this Court disclaimed the institutional competence to resolve that question, concluding that it should be answered through the democratic process. *See* 521 U.S. at 735.

[15] To be sure, as the Court observed in a footnote in *Babbitt* v. *Sweet Home Chapter of Communities for a Great Oregon*, the rule of lenity does not necessarily "provide the standard for reviewing facial challenges to administrative regulations" in every case where "the governing statute authorizes criminal enforcement." 515 U.S. 687, 704 n.18 (1995). In other words, *Sweet Home* observed that the rule of lenity will not always trump *Chevron* deference, where such deference is appropriate. In that case, unlike this one, *Chevron* deference was due because the agency had been delegated, and had exercised, rulemaking authority to create the standards at issue. *See id.* at 703. As demonstrated below, *see infra* Part V, no such deference is warranted here; the question is simply whether the CSA makes it a crime, or empowers the Attorney General to make it a crime, to prescribe drugs as authorized by the ODWDA. As a long-established tool for determining congressional intent in criminal statutes and a settled part of the interpretive background against which Congress legislates, the rule of lenity is obviously relevant to that inquiry.

As *Glucksberg* explained, "Americans today are increasingly likely to die in institutions, from chronic illnesses. Public concern and democratic action are therefore sharply focused on how best to protect dignity and independence at the end of life ...." 521 U.S. at 716 (citation omitted). "Thus, the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide." *Id.* at 719. The Court specifically noted Oregon's choice to permit physician-assisted suicide "for competent, terminally ill adults." *Id.* at 717. And the Court's ultimate decision not to recognize a broad due process right to assistance in committing suicide rested in part on its reluctance to cut off that democratic debate and exploration of different approaches among the States: "Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735.

Justice O'Connor's concurrence similarly noted: "As the Court recognizes, States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues.... In such circumstances, 'the ... challenging task of crafting appropriate procedures for safeguarding ... liberty interests is entrusted to the "laboratory" of the States ... in the first instance.'" 521 U.S. at 737 (O'Connor, J., concurring) (citations omitted). And Justice Souter expressly rested his concurrence in the judgment on the proposition that the Court "should ... stay its hand to allow reasonable legislative consideration" of the issue of physician-assisted suicide. *Id.* at 789 (Souter, J., concurring in the judgment). He reasoned that only "experimentation in some jurisdictions" can "confirm[] or discredit[] the concerns" about possible abuse of physician-assisted suicide, and anticipated that the Court's restraint would open the

door for "just such experimentation [to] be attempted in some of the States." *Id.* at 787-788 (citing the ODWDA).[16]

These same considerations counsel strongly against interpreting the CSA to permit an unelected executive official, via administrative fiat, to foreclose all such exploration by the States. In Justice Brandeis' famous words:

> To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.

New State Ice Co. v. *Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

Only efforts like Oregon's can resolve the "serious factual controversy" over the wisdom and feasibility of regulated physician-assisted suicide—and, ultimately, the constitutional question of the proper balance between the governmental interest in protecting the disabled and vulnerable and the individual's interest in avoiding suffering and loss of dignity at the end of life. *Glucksberg*, 521 U.S. at 786 (Souter, J., concurring in the judgment); *see also id.* at 737 (O'Connor, J., concurring). The Directive would eliminate the only opportunity to learn, through experience with various approaches to regulation and monitoring of physician-

[16] In *Glucksberg*, the Department of Justice advocated this cautious approach, arguing that state legislatures, rather than the federal government, should determine whether the terminally ill should be permitted to request life-ending medication. *See* Br. of United States as Amicus Curiae Supporting Petitioners, *Washington* v. *Glucksberg* (1996), 1996 WL 663185, at *10 ("Because terminal illness potentially affects all Americans . . . there is every reason to believe that state legislatures will address the urgent issues involved in this case in a fair and impartial way."); *id.* at *27 n.3 ("States have begun to consider anew the issue of physician assisted suicide, and there is no indication that the political processes are malfunctioning.") (citing Oregon's approval of the ODWDA).

assisted suicide, whether opponents' concerns about its use are valid, and which approach best accommodates the deeply important interests implicated. Oregon's choice to permit regulated physician-assisted suicide in limited circumstances, on the other hand, provides the chance to obtain experience and empirical data that can help answer those questions.[17]

This Court's task, of course, is not to evaluate the wisdom of Oregon's choice, but to determine whether the CSA precludes it from making that choice. That task of statutory interpretation should be informed by a recognition of the Directive's effect. The Attorney General's expansive construction of his own power under the CSA would prematurely cut off democratic exploration and debate among the States on the difficult questions surrounding end-of-life care—and it would do so by making doctors' compliance with the ODWDA a federal crime. Basic principles of statutory construction support the view that if Congress had intended to take such a radical step—or to grant the Attorney General the authority to do so—it would have given a clearer indication of its intent than the Attorney General can find in the CSA. Because the Attorney General's reading is not authorized by the CSA, this Court should decline to adopt it, and instead permit the debate over physician-assisted suicide "to continue, as it should in a democratic society." *Glucksberg*, 521 U.S. at 735.

[17] The ODWDA requires detailed recordkeeping by physicians, *see* Or. Rev. Stat. § 127.855, and requires that the Oregon Department of Health Services prepare an annual report analyzing the state's experience with the ODWDA, *see id.* § 127.865. Oregon Health Services has thus far issued seven such annual reports, which contain detailed information on the demographic characteristics of the patients who requested prescriptions under the ODWDA and the reasons for their choice. *See* Oregon Dep't of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005). These reports are a valuable source of information about the experience of legalized, regulated physician-assisted suicide.

V. THE ATTORNEY GENERAL'S DIRECTIVE WARRANTS NO DEFERENCE

Because, for all the reasons given above, the Directive is not a permissible construction of the CSA, this Court need not reach the Attorney General's contention (Br. 21) that the Directive deserves deference.[18] Even if the Court were to conclude that the Attorney General's interpretation is not precluded by the CSA, however, the Court should reject his claim to deference—and, for the reasons above, should find his reading of the statute unpersuasive.

Although the Attorney General now invokes *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Directive—an interpretive rule issued without notice and comment, on a subject as to which the Attorney General has no relevant expertise—is very far from the type of agency pronouncement entitled to *Chevron* deference.[19] Such deference is warranted only when "Congress delegated authority to the agency generally to make rules carrying the force of law," such as by "adjudication or notice-and-comment rulemaking," and when "the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States* v. *Mead Corp.*, 533 U.S. 218, 226-227 (2001). "It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *Id.* at 230.

That test is not met here. The Directive was issued not only without notice and comment, but without any other

[18] *See MCI Telecommunications Corp.* v. *AT&T*, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear . . . .").

[19] Indeed, in the proceedings below, the Attorney General did not even attempt to claim *Chevron* deference, instead arguing only for the lesser standard of deference articulated in *Skidmore* v. *Swift & Co.*, 323 U.S. 134 (1944). *See* Ashcroft App. Br. 23-24.

procedural formalities that would "tend[ ] to foster . . . fairness and deliberation." 533 U.S. at 230. The Directive relies solely on a memorandum from the Office of Legal Counsel of which Oregon was given no notice, and to which it was given no opportunity to respond. Nor is there any indication in the CSA that Congress intended to confer the kind of broad authority that would warrant deference in the absence of notice-and-comment procedures.[20] The Directive thus presents "a case far removed not only from notice-and-comment process, but from any other circumstances reasonably suggesting that Congress" would have intended the Directive to enjoy *Chevron* deference. *Id.* at 231.

Accordingly, the Directive should receive only whatever deference is due under *Skidmore* v. *Swift & Co.*, 323 U.S. 134 (1944). *See, e.g., Mead*, 533 U.S. at 234; *Christensen* v. *Harris County*, 529 U.S. 576, 587 (2000). Under *Skidmore*, the degree of deference afforded an agency pronouncement "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." 323 U.S. at 140.

The Directive fails when judged against these criteria. *First*, the Directive bears no hallmarks of the kind of deliberative process that would entitle it to respect. The Attorney General did not inform Oregon of his deliberations, solicit Oregon's views, or take into account the empirical data Oregon had collected in the four years that the ODWDA had been in effect. *Second*, "[a]n agency interpretation . . . which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held

[20] By contrast, Congress specifically provided elaborate procedures for altering the schedule of controlled substances—provisions that, as this Court recognized in *Touby*, rendered tolerable the statute's grant of authority to the Attorney General, within the bounds set by the CSA, to make rules that render criminal the possession and distribution of such substances. *See* 500 U.S. at 166-167. The absence of similar procedures here is compelling evidence that no such power was contemplated.

agency view." *INS* v. *Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (citation omitted). Here, the Directive represents a recent and sharp reversal of course from the previous Attorney General's views. *See supra* Part I. *Third*, the Attorney General has no relevant scientific or medical expertise that would entitle him to deference on the question whether physician-assisted suicide is a legitimate medical practice, *see Mead Corp.*, 533 U.S. at 235—indeed, Congress has expressly refused to give the Attorney General the power to resolve scientific or medical questions under the CSA, instead assigning that authority to the Secretary of Health and Human Services, *see* 21 U.S.C. § 811(b).

The Attorney General erroneously contends, relying on *Auer* v. *Robbins*, 519 U.S. 452 (1997), that he is entitled to a particularly high degree of deference because the Directive interprets both the CSA and the 1971 regulation. As the Attorney General acknowledges (Br. 5, 17 n.6), however, the regulation's "legitimate medical purpose" standard merely restates the statute's "course of professional practice" requirement. The question is therefore whether the Directive is a permissible interpretation of the *statute*. It would make no sense, in resolving that question, to give the Attorney General greater deference than he would otherwise receive, simply because of the existence of a regulation that echoes the statutory standard.

As *Auer* itself makes clear, the primary justification for special deference to an agency's interpretation of its own regulation is that, as the drafter of the regulation, the agency is in the best position to know what it means. *See* 519 U.S. at 461 (finding that deference was due because the concept at issue was "a creature of the Secretary's own regulations"); *see also, e.g.*, *Martin* v. *OSHRC*, 499 U.S. 144, 152-153 (1991). Similarly, where the regulation being interpreted is part of "'a complex and highly technical regulatory program'" established by the agency, the agency has special relevant expertise entitling its views to respect. *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994) (citation omitted). Neither justification for special deference has any

force here, where the regulation merely restates the statutory standard, and Congress has refused to give the Attorney General the power to resolve medical and scientific questions of the kind addressed by the Directive.[21]

Finally, whatever standard is applied, the very nature of the question that the Directive purports to resolve counsels strongly against granting the Attorney General the deference he seeks. As the Court has explained, "we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of [great] economic and political magnitude to an administrative agency." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (holding that the Food, Drug, and Cosmetic Act did not grant the FDA the authority to regulate tobacco products). The more important and politically fraught the question, the less likely it is that Congress would grant an agency the power to resolve it without making the delegation of authority clear. *See id.*; *see also MCI*, 512 U.S. at 231; *Kent* v. *Dulles*, 357 U.S. 116, 129 (1958). Put another way, "Congress does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (holding that, for the Clean Air Act to grant the EPA authority to consider costs in setting air quality standards, the "textual commitment must be a clear one" and finding no

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[21] As several Justices have noted, application of the *Auer* rule may in some cases "disserve[] the very purpose behind the delegation of lawmaking power to administrative agencies" by giving the agency an incentive to promulgate vague regulations and supply the necessary detail through procedures that lack the constraints imposed by notice-and-comment rulemaking. *Thomas Jefferson Univ.*, 512 U.S. at 525 (Thomas, J., dissenting, joined by Stevens, O'Connor, and Ginsburg, JJ.); *see generally* John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 Colum. L. Rev. 612, 618, 654-660 (1996). That concern is even more powerful here, where the interpretation of the regulation criminalizes conduct not clearly made a crime by either the statute or the regulation.

such clear delegation of authority). That is particularly true where, as here, the agency's assertion of power "alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste*, 531 U.S. at 173 (refusing to grant *Chevron* deference to an administrative interpretation of a statute that altered the federal-state balance).

These principles should govern here. Physician-assisted suicide is precisely the kind of important and divisive political question that Congress does not delegate to an administrative agency by implication. Yet the Directive arrogates to a single unelected executive official the authority to decide that question and to cut short the democratic debate on end-of-life care among the States. Only a much clearer statement would justify the conclusion that Congress intended to take such a momentous step. Because the CSA does not grant the Attorney General the power to resolve the profound medical, political, and moral questions posed by physician-assisted suicide, the Directive should be rejected.

CONCLUSION

The judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

Respectfully submitted,

DAVID W. OGDEN
Counsel of Record
PAUL R.Q. WOLFSON
DAVID S. MENDEL
DANIELLE SPINELLI
HEATHER ELLIOTT
NORA FREEMAN ENGSTROM
WILMER CUTLER PICKERING
HALE AND DORR LLP
2445 M Street, N.W.
Washington, DC 20037
(202) 663-6000

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Supreme Court of the United States

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Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* SURVIVING FAMILY MEMBERS IN SUPPORT OF RESPONDENTS

ROBERT A. FREE
Counsel of Record
KATRIN E. FRANK
MACDONALD HOAGUE & BAYLESS
1500 Hoge Building
705 Second Avenue
Seattle, WA 98104
(206) 622-1604

Attorneys for Amici Curiae Surviving Family Members

195453

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

Page

TABLE OF CITED AUTHORITIES ii

I. STATEMENT OF *AMICI CURIAE* 1

II. SUMMARY OF ARGUMENT 5

III. THE ATTORNEY GENERAL'S CONCLUSION THAT OREGON'S LAW AUTHORIZES ILLEGITIMATE MEDICAL PRACTICES AND THREATENS THE PUBLIC HEALTH AND SAFETY IS ARBITRARY AND CAPRICIOUS 6

A. The Declarations of Survivors Whose Family Members Utilized Oregon's Law Demonstrate the Legitimate Public Interest and Public Health and Safety Concerns Served by the Death with Dignity Act. 7

B. The Declarations of Survivors Whose Family Members Could Not Utilize Oregon's Law Demonstrate the Legitimate Public Interest and Public Health and Safety Concerns Served by the Death with Dignity Act. 15

IV. CONCLUSION 23

TABLE OF CITED AUTHORITIES

Page

Cases:

Chevron USA v. Natural Resources Defense Council, 467 U.S. 837 (1984) 6

Northwest Natural Gas Co. v. Portland, 300 Ore. 291 (1985) 7

Washington v. Glucksberg, 521 U.S. 702 (1997) ... 1

Webster v. Reproductive Health Services, 492 U.S. 490, 106 L. Ed. 2d 410, 109 S. Ct. 3040 (1989) 1

Statute:

21 U.S.C. § 823(f)(5) 7

Other Authorities:

Battin, M.P., *The Least Worst Death* (1994) 5, 7

Block, Susan D., *Patient's Request to Hasten Death*, 154 Archives Internal Med. 2039 (1994) 5

Burnell, George M., *Final Choices: To Live or to Die in an Age of Medical Technology* (1993) ... 5

Chevron USA v. Natural Resources Defense Council, 467 U.S. 837 (1984) 6

Compassion in Dying v. State of Washington, 79 F.3d 790 (9th Cir. 1996), rev'd. *Washington v. Glucksberg*, 521 U.S. 702 (1997) 1

Cited Authorities

Page

Farnsworth, C., *Vancouver AIDS Suicides Botched*, "N.Y. Times," June 14, 1994 ..... 5, 19

Fifth Annual Report on Oregon's Death with Dignity Act, Oregon Dept. of Human Services, Office of Disease Prevention and Epidemiology (Mar. 6, 2003) 14

Fourth Annual Report on Oregon's Death with Dignity Act, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 6, 2002) 14

Hedberg, Katrina, et al., *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 New Eng. J. Med. 961 (2003) 14

Jamison, Stephen, Ph.D., *Final Acts of Love: Families, Friends, and Assisted Dying* 169 (1995) 5, 24

Kolata, G., *AIDS Patients Seek Solace in Suicide But Many Risk Added Pain in Failure*, "N.Y. Times," June 14, 1994 ..... 5, 24

Kreimer, 44 Am. U. L. Rev. at 831 7

Lavery, James V., et al., *Origins of the Desire for Euthanasia and Assisted Suicide in People With HIV-1 or AIDS: A Qualitative Study*, LANCET, Vol. 358, No. 9279 (Aug. 4, 2001) 5

Cited Authorities

Page

Lavery, James V., et al., *Desire for Physician-Assisted Suicide: Requests for a Better Death?*, Commentary, LANCET, Vol. 358, No. 9729 (2001) 5

Mayo, D. and Gunderson, M., *Vitalism Revitalized: Vulnerable Populations, Prejudice, and Physician-Assisted Death*, The Hastings Center Report (July-Aug. 2002, pp. 14-21) 10

Nuland, Sherwin B., *How We Die: Reflections on Life's Final Chapter* (1994) 5

Oregon's Death With Dignity Act: The First Year's Experience, Dept. of Human Resources, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 18, 1999) 14

Oregon's Death With Dignity Act: The Second Year's Experience, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 23, 2000) 14

Oregon's Death With Dignity Act: Three Years of Legalized Physician-Assisted Suicide, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 22, 2001) 14

Quill, Timothy E., *Death and Dignity: Making Choices and Taking Charge* (1993) 5

Quill, Timothy E., *A Case of Individualized Decision-making*, 324 New Eng. J. Med. 691 (1991) 5

Cited Authorities

Page

Quill, Timothy E., *A Midwife Through The Dying Process* (1996) 5, 15, 23

Rachels, James, *The End of Life* (1986) 5

Rollin, Betty, *Last Wish* (1985) 5

Seventh Annual Report on Oregon's Death With Dignity Act, Oregon Dept. of Human Services, Office of Disease Prevention and Epidemiology (Mar. 10, 2005) 14

Shavelson, Lonny, *A Chosen Death: The Dying Confront Assisted Suicide* 677 (1995) 5, 19, 24

Singer, Peter, *Rethinking Life and Death* (1994) .. 5

Sixth Annual Report on Oregon's Death With Dignity Act, Oregon Dept. of Human Services, Office of Disease Prevention and Epidemiology (Mar. 10, 2004) 14

Solomon, A., *A Death of One's Own*, "The New Yorker," May 22, 1995 ..... 5, 19

Sullivan, Amy D. et al., *Legalized Physician-Assisted Suicide in Oregon 1998-2000*, 344 New Eng. J. Med. 605 (2001) 14

The New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context 40* (1994) .. 7

I. STATEMENT OF *AMICI CURIAE*

The *amici curiae* is composed of 17 distinct individuals – not an organization, a religious group, or a group of politicians.[1] The *amici* consists of six family members of individuals who experienced the positive aspects of physician-assisted dying under Oregon's Death with Dignity Act and eleven family members of individuals who experienced unnecessarily painful, traumatic deaths in the absence of physician-assisted dying. They submit this Brief in support of Plaintiffs' effort to preserve the rights afforded them by Oregon's Death with Dignity Act ("ODWDA").[2] The family members[3] are the voices of their deceased loved ones, describing for the Court the differing realities of what happens to families when a competent, terminally-ill person is granted or forbidden the choice of a hastened death. The individual experiences present the Court

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[1] This brief has been authored in its entirety by undersigned counsel for the *amici curiae*. No person or entity, other than the named *amici* and their counsel, made any monetary contribution to the preparation and submission of this brief. The parties have consented to the filing of this brief and their letters of consent are being lodged herewith.

[2] Consideration by the Court of statements similar to those filed herein are not without precedent. In *Webster v. Reproductive Health Services*, 492 U.S. 490, 106 L. Ed. 2d 410, 109 S. Ct. 3040 (1989), an *amicus* brief filed with and considered by the U.S. Supreme Court, entitled "Women Who Have Had Abortions, et al.," included declarations by numerous women who had experienced legal and illegal abortions. More recently, the Ninth Circuit and the U.S. Supreme Court considered the arguments and declarations of surviving family members of individuals suffering from terminal illnesses who hastened their own deaths, some resulting in tragedy because physician assistance was unavailable. *See Compassion in Dying v. State of Washington*, 79 F.3d 790, 834 n. 126 (9th Cir. 1996); *Washington v. Glucksberg*, 521 U.S. 702 (1997). As in *Webster*, *Compassion in Dying*, and *Glucksberg*, the declarations filed here contain relevant first-hand information by persons intimately familiar with the issues presented to the Court.

[3] The term "family member" includes spouses, children, parents, a cousin, and one partner involved in a close personal relationship.

with the emotional resonance of dying with and without physician assistance to hasten the process. In each case, the dying person strongly desired to hasten his or her impending death. Contrary to the Attorney General's contention, none was depressed. Some were successful in hastening death without the benefit of the provisions for a humane death provided by the ODWDA – they used plastic bags or chose guns. Some died slowly but "naturally," in agony and without dignity. Those who could use the Oregon Act died when and how they wanted, under medical care, peacefully, with loved ones present. The perspective of persons who have had recent experience with this issue is relevant and necessary to the Court's proper and full consideration.

Declarations of the 17 family members were attached as appendices to their amici brief filed in the Ninth Circuit. The group includes the following who wanted to hasten their death but who did not have the benefit of Oregon's Death with Dignity Act:

- a widow whose husband of 25 years shot himself in their front yard in order to end his debilitating pain (App. 1) ("App." numbers reference the appendices filed by *amici* at the Ninth Circuit);
- a daughter whose father shot himself in bed, with his wife sleeping in the next room, rather than endure the nausea, vomiting, and excruciating pain resulting from his prostate cancer (App. 2);
- a daughter whose father asphyxiated himself with carbon monoxide poisoning from a charcoal grill in his bedroom, rather than suffer debilitating weakness and suffocation from end-stage emphysema (App. 3);
- a daughter whose father, dying of lung cancer, went down to his basement and shot himself with a 12-gauge shotgun, knowing it was illegal for his family members to assist in a suicide (App. 4)

- a daughter whose mother was wasted by cancer to a mere 60 pounds before she swallowed morphine (App. 5);
- a son whose mother suffered from ALS (Lou Gehrig's disease), losing the ability to walk, talk, breathe calmly, eat whole foods, and go to the bathroom and who felt this disease was worse than her experience in the Holocaust because she was so alone in her agony (App. 6);
- the life partner of a man who died a painful death from AIDS in 1995, who wanted to hasten his death but could not because it was not then legal in Oregon (the partner, who now has late-stage AIDS, has received medication to hasten his death under Oregon's law) (App. 7);
- a daughter whose mother was dying from throat cancer and suffering from grand mal seizures (causing her head to swell up like a balloon); the mother decided to stop hydration and food because it was the only method of hastening death in which her physician would assist (App. 8);
- a daughter whose father lay dying, diapered, moaning in pain and begging to die, while the doctor refused morphine because it could kill him (App. 9);
- a son who was criminally prosecuted for helping his 88-year old father, dying of cancer, hold a plastic bag over his head (App. 10); and
- a mother who struggled to medically assist her 26 year old daughter to die, because a doctor's help was not available (App 11).

In juxtaposition to these horrific deaths, the declarants also include six whose family members were able to utilize the Death with Dignity Act. This group includes:

- a daughter whose mother utilized the ODWDA to hasten her impending death and died surrounded by her five children, their spouses, her sister, her nephew, and her long-time personal physician, peacefully looking out over the Willamette River, in a room filled with love (App. 12);
- a husband whose wife of 25 years chose a hastened death rather than lingering under heavier and heavier doses of morphine treating her lung cancer pain and suffocating from the fluid in her lungs; with full support from her family, her clergyperson, her primary doctor, and other caregivers, she chose to hasten her death under the ODWDA (App. 13);
- a husband whose wife died under the ODWDA with her immediate family, a close friend, and two volunteers from Compassion in Dying of Oregon at her side – she died quickly and peacefully after saying goodbye to her loved ones, rather than continuing to suffer from pancreatic cancer, which had resulted in diabetes, physical debilitation, and moderately severe Parkinsonian-type tremors (App.14);
- a woman whose relative wrote two days before she died, which was the day before Thanksgiving: "On Thanksgiving, I hope everyone in my family will take time to feel thankful that I live in Oregon and have the means to escape this cancer before it gets any worse. I love you all." (App. 15);
- a widow whose husband died a few hours before obtaining the medication under the ODWDA that could end his life – who died in peace because he knew he finally had control over his life and death (App. 16);

- a daughter whose father died with his dignity in tact because he knew that under the ODWDA he had been approved to obtain medication to hasten his death (App. 17); and

The survivors are among a significant number of Americans who have witnessed loved ones die.[4] They give their names and sacrifice their privacy and that of their families to preserve their liberty and the liberty of others who are terminally ill and wish to die with dignity. With the combined personal experiences of this group, the *amici* has a profound interest in this litigation.

II. SUMMARY OF ARGUMENT

The *amici* support the District Court's and Court of Appeals' decision and counter the Attorney General's erroneous contention that permitting physicians to prescribe medication to hasten death, in certain limited situations, threatens the public

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[4] Various sources recount experiences of hundreds of Americans similar to the experiences of the 18 representative family members. M. Battin, *The Least Worst Death* (1994); G. Burnell, *Final Choices: To Live or to Die in an Age of Medical Technology* (1993); C. Farnsworth, *Vancouver AIDS Suicides Botched*, N.Y. Times, June 14, 1994 at C12; S. Jamison, *Final Acts of Love* (1995); G. Kolata, *AIDS Patients Seek Solace in Suicide But Many Risk Added Pain in Failure*, N.Y. Times, June 14, 1994 at C I ; S. Nuland, *How We Die: Reflections on Life's Final Chapter* (1994); T. Quill, *Death and Dignity: Making Choices and Taking Charge* (1993); T. Quill, *A Midwife Through the Dying Process* (1996); J. Rachels, *The End of Life* (1986); B. Rollin, *Last Wish* (1985); L. Shavelson, *A Chosen Death: The Dying Confront Assisted Suicide* (1995); P. Singer, *Rethinking Life and Death* (1994); A. Solomon, *A Death of One's Own*, "The New Yorker," May 22, 1995 at 54; James V. Lavery et al., *Origins of the Desire for Euthanasia and Assisted Suicide in People With HIV-1 or AIDS: A Qualitative Study*, LANCET, Vol. 358, No. 9279 (Aug. 4, 2001); James V. Lavery et al., *Desire for Physician-Assisted Suicide: Requests for a Better Death?*, Commentary, LANCET, Vol. 358, No. 9729 (2001); Susan D. Block, *Patient's Request to Hasten Death*, 154 Archives Internal Med. 2039 (1994); Timothy Quill, *A Case of Individualized Decision-making*, 324 New Eng. J. Med. 691, 694 (1991).

health and safety. The experiences of the survivors recounting the positive aspects of having a physician assist in a hastened death demonstrate the important legitimate public interest and public health and safety concerns served by the Oregon law. The accounts of the survivors whose family members were deprived of the legal choice to obtain medical assistance to hasten death illustrate the tragic and enduring consequences of denying such freedom. The declarations reveal that Oregon's approach reduces the tragic consequences that flow from violent suicides, from failed attempts to commit suicide, from subjecting compassionate family members who assist in suicide to criminal liability, and from prolonging physical and emotional suffering of terminally-ill patients.

III. THE ATTORNEY GENERAL'S CONCLUSION THAT OREGON'S LAW AUTHORIZES ILLEGITIMATE MEDICAL PRACTICES AND THREATENS THE PUBLIC HEALTH AND SAFETY IS ARBITRARY AND CAPRICIOUS

The Courts below found that Congress did not intend the Controlled Substances Act ("CSA") to override a state's decision concerning what constitutes legitimate medical practices. *Amici* supports this conclusion. However, if this Court finds that the Attorney General does have authority under the CSA to define what constitutes legitimate medical practices, then the Attorney General's conclusion that the ODWDA authorizes illegitimate medical practices is an arbitrary and capricious conclusion. The Supreme Court has determined that agency interpretations, directories, and regulations are "given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Chevron USA v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984).

The Attorney General argues that the CSA authorizes him to prevent physicians from legally prescribing controlled substances if he determines that it would be against the **public interest** and threatening to the **public health and safety**. The

CSA does authorize the Attorney General, in making that public interest determination, to consider "[s]uch other conduct which may threaten the public health and safety." 21 U.S.C. § 823(f)(5). The crux of the Attorney General's position is that Oregon's law threatens the public health and safety.

The Attorney General's position is refuted by the declarations of the Surviving Family Members, is not supported by other rational argument, and is therefore arbitrary and capricious.

A. The Declarations of Survivors Whose Family Members Utilized Oregon's Law Demonstrate the Legitimate Public Interest and Public Health and Safety Concerns Served by the Death with Dignity Act.

The ODWDA serves the public interest in several important ways that are well within the police power of the state to promote. *Northwest Natural Gas Co. v. Portland*, 300 Ore. 291, 297 (1985) (noting that the state has police power to ensure health and safety of the public). The individual experiences of several of the *amici* surviving family members illustrate one or more of the following important contributions made by the ODWDA:

- **The ODWDA relieves severe and prolonged suffering of some dying patients who would prefer death:**[5]

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[5] Despite new advances in pain treatment, an "irreducible core of patients are trapped in physical agony (if they are awake)." Kreimer, 44 Am. U.L. Rev. at 831, n.93. Pain cannot be controlled in 5% to 10% of cases. The New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context 40,* n. 18 (1994). Often, controlling pain sacrifices the patient's consciousness, which "is tantamount to causing death; the patient has no further conscious experience and thus can achieve no goods, experience no significant communication, satisfy no goals." M.P. Battin, *supra*, at 105.

- Alvin Davis describes his wife's choice to utilize the ODWDA:

  "It is possible to endure a great deal of pain and discomfort if one feels there is a purpose in doing so – that there may be a 'light at the end of the tunnel.' But when Norma learned from her oncologist early in July, 2001 that she had at most a few more weeks left to live, she decided she would prefer death on her own terms to a continuing, futile struggle ending in helplessness and misery. . . . [I]n those cases where the patient is suffering greatly and wishes to terminate his or her life before losing the ability to control what might happen, then the attempt by society to deny that right is, I believe, unspeakably cruel and arrogant." (App. 14)

- Robert Schwartz, suffering from late stage AIDS, has already obtained medication under the ODWDA rather than endure the pain suffered by his late partner:

  "During his final months [Roger] suffered from shortness of breath, full body pain, viral load of over one-million, CD4 count of less than 5 and general discomfort. He constantly said he had no relief from his medication. He also experienced temperature disregulation which caused him to be hot all of the time and he never found relief from it. . . . In my case I was diagnosed with HIV in the 1980s and I now have late stage AIDS. I completed the process under Oregon's Death with Dignity Act and now have the lethal dose of medication to hasten my death. I do not know if I will take the medication, but knowing I have it available affords me great comfort and ease of mind. I only wish Oregon's law was available to

Roger. He may not have died the tragic death he did if he had the legal option to hasten his death." (App. 7)

- **The ODWDA promotes public safety and order by averting violent, ghastly, and often unsuccessful efforts to hasten impending death by patients who previously could not make use of the ODWDA:**

  - Tania Bloom writes of her father's death by gunshot:

    "My son-in-law had the unfortunate and unpleasant task of cleaning my father's splattered brains off the basement walls. This memory lives with him to this day. . . . If Oregon's law had been in effect in Washington my father's tragic and violent death could have been avoided." (App. 4)

  - Dr. Marcia Angell, M.D., a lecturer at Harvard, writes about her father's gunshot death:

    "If physician-assisted-dying had been available to my father, as it is to the people of Oregon, I have no doubt that he would have chosen a less violent and lonely death. My mother could have been brought around to accepting his decision, death could have been peaceful, and his family could have been with him. If he knew he had the option to get help in ending his life at any time in the future, he probably would have chosen to live longer. That night would not have been his last chance." (App. 2)

- **The ODWDA provides safeguards that ensure a decision to hasten death is made knowingly, voluntarily, and with proper medical advice and assistance after due consideration[6]:**
  - Scott Rice was involved in his wife's utilization of the ODWDA in 2000:

    "She went through an extensive screening process over a two-week period which involved her having three sessions with her primary doctor, an interview with the chief of ethics of our HMO, and the review by a second doctor outside the HMO. There was no doubt from anyone that she was competent and not depressed. Her treatment options were discussed and reviewed with her over and over again. She was given assistance with hospice care and pain management. We were encouraged to share her decision with our family members, which we did. We also took time to discuss her desires with her clergy person. After each meeting and discussion Colleen's resolve to hasten her death strengthened." (App. 13)

- **The ODWDA advances the public interest in protecting families by relieving family members of the pressure to assist their loved ones to hasten death illegally:**
  - Julie McMurchie writes about her mother, who utilized the ODWDA:

[6] *See* D. Mayo and M. Gunderson, *Vitalism Revitalized: Vulnerable Populations, Prejudice, and Physician-Assisted Death,* The Hastings Center Report (July-Aug. 2002, pp. 14-21). This paper refutes the argument that ODWDA is not in the best interest of people with disabilities, as posited by organizations such as Not Dead Yet. The risk of coercion is already present in states other than Oregon and arguments against ODWDA deny that people with disabilities are capable of choosing intelligently and authentically.

"I am proud to have supported my mother in the final deliberate act she had in her life... Oregon's law gave my family and me something special and it allowed my mother to die with dignity and grace." (App. 12)

- Patty Rosen helped her daughter die in Oregon, before the ODWDA took effect:

  "If Oregon's law had been in effect at the time of my daughter's death she would not have had to endure the long, anguishing months of pain and suffering caused by her cancer. She would not have had to add to her pain by worrying about whether I might be punished for assisting her. I too would not have had to agonize for months over whether to assist her. If Oregon's law had been in effect in 1986 my daughter's dying would have been free from fear. I know in my heart she would have chosen to use Oregon's law and our family would have been at her bedside sharing all our love without fear of prosecution." (App. 11)

- **The ODWDA protects the dignity, privacy, and autonomy of patients:**
  - Scott Rice writes:

    "If my wife had not been able to access her right to die with dignity under the law because her physicians feared they would be prosecuted, her rights would have been taken away from her without recourse and she would have died a terrible death – one that she did not want to experience and that no one should have to experience. She did not want that for herself or for us who would have had to stand by watching her drown in her own fluid." (App. 13)

- Julie McMurchie writes about her mother's decision to utilize the ODWDA:

  "She often said that she feared the loss of control over her life and that when she started the process to use Oregon's law she found a great deal of comfort and ease of mind. She would often talk about her sister's death, which was an agonizingly long and painful death because her sister, who was unable to use Oregon's law because she was not a resident of Oregon. My mother vowed she would not go through the same dying process as did her sister." (App. 12)

- Beverly Heitz describes the benefits of the ODWDA even though her husband died a few hours before obtaining the prescribed medication:

  "While I wish Arnie had started the process sooner so that he could fulfill his wish, I am convinced Arnie was helped tremendously just knowing assisted suicide was an option for him. Arnie's daughter also saw a change in her father after he knew a prescription would be written for him under the law. He talked more about his death and he asked her to take care of me. He told his daughter that he knew he didn't have control over anything else anymore, but at least he had control over his death. Others told me that after Arnie knew he would get his prescription he found peace of mind because he wanted control over his life and death. . . . Arnie's decision to use the law profoundly affected my life. Arnie was a very special person and the bravest man I think God ever put on this earth. He taught me a lot about acceptance and a lot about 'letting go,' although I'm still stumbling through all of it." (App. 16)

- Sue Parks Hilden discusses her father's utilization of the ODWDA:

  "He often told me that he found great comfort going through the process of obtaining the medication. He said it was very useful and gave him ease of mind. It always gave his family, in particular me, time with him that I might not have otherwise have had. He almost completed the process of getting the medication before he died. He did not have the medication in his possession on the day he died, but he died peacefully at home surrounded by his family." (App. 17)

- Laura Boessenroth describes what her relative told her about her decision to utilize the ODWDA:

  "She told me she was very relieved to know that the law would be available to her because, now that her death was eminent. She told me she was relieved about her decision to consider using Oregon's law to facilitate a dignified end to her agony. She was ecstatic to be able to have present medical personnel present at her death who would monitor the process, offer comfort and their expertise. She was 'happy' with her plan, and because her life had been reduced to few truly happy moments, she considered the opportunity to have this small amount of control and peace of mind to be a gift to her and all who loved her." (App. 15)

Defendant has failed to provide *any* evidence of how the physicians or decedents who since 1997 utilized and complied with Oregon's law have threatened the public health and safety. There is no evidence that someone's hastened death was not voluntary or was under duress. There is no evidence that someone's hastened death occurred when the underlying illness was not terminal. There is no evidence that someone hastened

death because he or she was depressed or lacked knowledge about ameliorating pain. To the contrary, the declarations of surviving family members of patients who utilized Oregon's law are evidence that doctors and patients who complied with Oregon's law were able to achieve desired peaceful and dignified deaths, immeasurably helping both the dying persons and their family members and *hurting no one.*[7]

It will benefit all Americans to permit Oregon to continue experimenting with this vital question facing every human: how to die in peace and dignity. Citizens may disagree about the issue, but that does not mean that Oregon's position threatens the public health and safety.

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[7] *See Oregon's Death With Dignity Act: The First Year's Experience*, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 18, 1999); *Oregon's Death With Dignity Act: The Second Year's Experience*, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 23, 2000); *Oregon's Death With Dignity Act: Three Years of Legalized Physician-Assisted Suicide*, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 22, 2001); *Fourth Annual Report on Oregon's Death with Dignity Act*, Dept. of Human Services, Oregon Health Div., Center for Disease Prevention and Epidemiology (Feb. 6, 2002); *see also* Amy D. Sullivan et al., *Legalized Physician-Assisted Suicide in Oregon 1998-2000*, 344 New Eng. J. Med. 605 (2001). *Fifth Annual Report on Oregon's Death with Dignity Act*, Oregon Dept. of Human Services, Office of Disease Prevention and Epidemiology (Mar. 6, 2003); *Sixth Annual Report on Oregon's Death with Dignity Act*, Oregon Dept. of Human Services, Office of Disease Prevention and Epidemiology (Mar. 10, 2004); *Seventh Annual Report on Oregon's Death with Dignity Act*, Oregon Dept. of Human Services, Office of Disease Prevention and Epidemiology (Mar. 10, 2005); *see also* Katrina Hedberg et al., *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 New Eng. J. Med. 961 (2003).

B. The Declarations of Survivors Whose Family Members Could Not Utilize Oregon's Law Demonstrate the Legitimate Public Interest and Public Health and Safety Concerns Served by the Death with Dignity Act.

Several declarations of *amici* establish that the Oregon Act works as intended and that prior to its enactment real people suffered real harm that could not be alleviated by medication or therapy. The individual experiences of surviving family members illustrate one or more of the following harms to the public interest that the position of the United States would inflict by effectively reinstating the law in existence before the passage of Oregon's Death with Dignity Act:

- **Prior law resulted in untold pain, agony, and suffering for some dying patients who would prefer death; a slow, debilitating death is often accompanied by a profound loss of dignity and sense of self.**[8]

- Stewart Florsheim describes his mother's condition shortly before her death:

  "During the course of the disease [ALS/Lou Gehrig's disease], my mother suffered greatly. Over a short period of time, she lost the ability to walk and to swallow whole foods. Breathing became more and more difficult, as the muscles in her chest weakened. She used a Bi-Pap machine to assist her breathing. When that no longer was effective, the doctor recommended that she stop using the machine, and step up the dose of morphine to calm her breathing. At the end, she

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[8] T. Quill, *A Midwife Through the Dying Process* (1996) at 197 ("Often, doctors undermedicate dying patients' pain or shortness of breath because of the legal risks [both exaggerated and real] associated with overmedicating.")

started to lose her ability to talk. She became increasingly anxious because she felt as if she were suffocating. Because eating became a chore, she lost interest in food and became thin as a rail. That – in combination with the morphine – made her so constipated that her nurse had to come in many times to evacuate her bowels by hand. It was so painful to her that she screamed out... Toward the end of her life, she said that having this disease was worse than going through the Holocaust because she was alone in her agony. No one could really know how much she suffered." (App. 6)

- Leanne Gallison describes her mother's lung cancer:

  "Sharp pains developed in her chest and her spine. Terrifying episodes of shortness of breath increased. Chemotherapy made her horribly ill, nauseated around the clock. At this time, she began to have seizures. Tumors were discovered in her brain. Radiation was added to treat her brain but this resulted in my mother becoming completely flattened with no stamina, no energy... On her bad days, she would ask me, 'How am I going to get out of here?' And, 'I want to go, and I want to go NOW!' She weighed about 60 pounds." (App. 5)

- Linda Kilcrease and her four siblings watched their mother die from throat cancer:

  "We watched as her head blew up like a balloon, forcing her eyes closed, when the blood first began to back-up and could not drain. We watched as her heart beat so hard and fast, nearly ripping through her chest, trying to get blood into her head. The hospital staff gave us heartbeat and

blood pressure monitors, and we watched the wild fluctuations in vital statistics. We learned how to position Mom's head so her heart would calm down. We watched her change from a robust woman into a shriveled-up skeleton... It was torture for everyone, but especially for Mom... Those who say that pain medication and psychiatric help is all that is needed to help someone facing death have it all wrong. Neither would be of any use to my mother." (App. 8)

- Gail Bereny could not obtain help for her father's pain:

  "My father's pain was severe and unrelenting. Almost worse was his loss of dignity. As my father lay dying he was completely lucid and aware that he was diapered, weak, and needed help for even basic tasks. Dignity was very important to him, and the fact that he knew what was going on was terrible. He moaned in pain, begging to die. I called the doctor's office, crying, begging him to relieve Dad's pain. He refused, saying morphine would kill him." (App. 9)

- **Prior law caused some patients to choose a violent, often gruesome manner of hastening death; these acts are generally committed alone, without family present.**

  - Patsy McGeorge was in the house when her husband shot himself outside:

    "Mac did not want to be a sedated vegetable. Following an almost 24 hour drugged stupor, he decided that was not the answer. . . . After a brief and very personal conversation, he gave me the note he had carried for months, attesting to the fact that his decision was his own; kissed me

goodbye; went into the front yard; put a shotgun in his mouth and pulled the trigger. Since a peaceful death was not available, this was his way to insure death with the dignity he valued so highly. Two months later I was emotionally wrenched by finding a portion of his upper dental plate 50 feet from the site of his death – a testament to the violent alternative he was forced to choose... I wish I could have been with him at the end, but he said no, 'it will be messy.' (App. 1)

- Dr. Angell describes her father's suicide:

  "At the time my father killed himself, he was living with my mother near Orlando, Florida. My mother was a housewife who had always been dependent on him. Now it was the other way around. The day before his death, he fell while walking from the bed to the bathroom. My mother was unable to lift him, so she called the emergency medical technicians. They lifted him onto the bed and said they would return the next day to take him to the hospital to make certain he had not fractured a bone. I believe he decided to kill himself that night because it might be his last chance to do it. He had always kept a pistol in his bedside table. If he went to the hospital the next day, he would be without it and he might never again have the option of ending his own life. My mother was sleeping in the next room, and had to bear the shock of finding his body. If he had told her of his intentions, she would have stopped him, as she later told me. So he did not tell her. Later, I could see from the trajectory of the bullet that he had turned in such a way that the bullet could not have gone through the wall and harmed her." (App. 2)

- Leslie Ghan discovered her father after his suicide:

  "He discussed his desire to hasten his death with me on several occasions and I did not know how to advise him. Starving himself did not seem like an easy or peaceful option. He believed that his doctor would not assist him in any way. My father decided to take matters into his own hands. He went out with great difficulty and with his oxygen and bought a charcoal grill and charcoal. He assembled the grill and put it in his bedroom. Then he sealed the windows and door and lit the charcoal and lay down on the bed. I knew nothing about this plan. I went to his home the next day because he did not answer his phone and found a note on the table that said I should not go into the bedroom. I was shaking and crying and called the police. The coroner said he died of carbon monoxide poisoning and that it was probably a peaceful death. I will never forget that he had to do this all alone, that I couldn't be there." (App. 3)

- **Prior law resulted in the failure of some attempts to hasten death, due to the absence of trained medical care – sometimes leaving the patient in worse condition than before the attempt.** [9]

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[9] L. Shavelson, *supra*, at 126 ("From safer sleeping pills to air bags in cars, science had made killing yourself without professional help a tremendously difficult task – and a mission fraught with the potential for ghastly errors.") *See* C. Farnsworth, *Vancouver AIDS Suicides Botched*, "N.Y. Times," June 14, 1994 at C12 (of 34 assisted suicides studied in Vancouver, B.C. [which, similar to the U.S., bans physician assisted suicide], half were "botched, increasing suffering when the aim was to alleviate it."); Andrew Solomon, *A Death of One's Own*, "The New Yorker," May 22, 1995, at 57

I heard of suicides as grueling as the diseases they were meant

(Cont'd)

- **Prior law resulted in some family members feeling compelled to assist their loved ones to hasten death, with concomitant fear and hiding, guilt, and occasional criminal investigation and prosecution.**
  - William Meyer describes his prosecution for his involvement in his father's death in Connecticut:

    "After my father and I met with my father's doctor of 25 years, my father decided that he would take sleeping pills and place a plastic bag over his head, as described in the book Final Exit. My father's first attempt at this failed when his reflex action, which comes of feeling suffocated, caused him to pull off the plastic bag. Since my father wanted to protect me from getting into trouble with the law, he instructed me to leave the house immediately after he placed the plastic bag over his head. He was alone. The next morning, when I returned, I found him awake and distressed that he was still alive. He pleaded with me to do everything possible to end his life that evening. This was undoubtedly the most difficult day of my life. He consulted with his doctor and was advised that I could hold my father's hands so the reflex action would not remove the plastic bag. My father and I followed this procedure and he was able to end his life. . . . I was arrested and charged by the police with second degree

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(Cont'd)

to terminate. In some cases, irreplaceable pills were regurgitated. "My husband had to just eat his vomit," one woman said. "He was that determined. But then he threw up again. We waited about an hour; then he downed it all again and I put a plastic bag over his head so he would suffocate before he got sick, and he finally died. He'd been through so much, and that whole disgusting, humiliating business was the living end."

manslaughter. If convicted, I faced ten years in prison. At a hearing in December 1994, before a Superior Court judge in Hartford, Connecticut, two ministers and several friends spoke on my behalf. Numerous people, including eleven ministers and eighteen doctors and nurses wrote to the judge to support me. Even though the District Attorney pleaded that my case go to trial, the judge stated that although I had broken the law, I was following my father's wishes. I was given two years "accelerated rehabilitation" and after two years, all charges were dropped with no record." (App. 10)

- Patty Rosen describes her agony being present at her daughter's suicide in Oregon before the ODWDA took effect:

  "Jody, bedridden from the inexorable growth of the [bone] cancer, felt trapped in her body that would barely work. She slept with the aid of medication almost 23 hours each day. Even in sleep her face reflected the pain she was constantly enduring. She was also losing her sight, experienced excruciating pain from total bowel obstruction, and shuddered in pain whenever someone touched her because now there were also tumors, just below the surface of her skin, that inflamed her nerves and caused even more severe pain... My daughter was dying. She knew it and she was ready to die sooner than later. She was rational, calm, and ready to die. However, in 1986 it was illegal for anyone, in any state in the United States, to assist in hastening a death. Jody said to me that she 'should be able to talk with [her] doctor and plan this, not ask [you].' She said to me, 'Mom, what if you go to prison? What will happen to you?' This concern and worry

made her small face, already marred with the sunken eyes of the near dead, take on an incredibly distressed, painful appearance. Her trust and faith in me made me humble and I vowed I would not let her continue to suffer merely because of what might happen to me if I assisted her. . . . When it was time for Jody to hasten her death she calmly and determinedly swallowed all of the medication we had gathered, took a few sips of water, kissed me, and said, 'See you later Mom.' She then closed her eyes and went to sleep. At that moment I went into a pure panic. I thought, 'What if I failed? What if she regains consciousness?' If this didn't work she might even be worse off than before and an even more consequence; I would have failed her. I then gave her all the I.V. medications I could pump into her stilled body. I moaned, sobbed, prayed, and kept pushing the drugs into her body. I was as desperate as I had ever been in my life. . . . The silence came ten hours after we had started the process. My daughter finally stopped breathing. Her year and a half of pain, suffering, rage, and hopelessness had ended. I crawled into her bed, gathered her still body into my arms; at last able to hold my daughter without hurting her. I stroked her hair while rocking her gently. I was able to surrender to my own grief knowing that my young, brave and wise daughter, Jody Lynn Grape, age 26, found her peace on October 30, 1986 at 1:30 p.m." (App. 11)

- Prior law resulted in suffering, guilt, anger, and remorse for some surviving family members.
  - Gail Bereny writes about her father's slow, "natural" death:

    "I felt very guilty then, and feel guilty now, about Dad's terrible death. I feel guilty that he died in so much pain and with no dignity left. The doctor had the means to give him a gentle, painless death. I have been left with frustration, anger, regret, and sadness. He had been a very good father." (App. 9)

  - Leanne Gallison describes her feelings about the end of her mother's life:

    "My mother's illness was awful for me because I was very close to her. I had nightmares for weeks prior to her death. She was so miserable and in a state that she never wanted to find herself in. In spite of my being a nurse, I felt helpless." (App. 5)

  - Patsy McGeorge describes her current reaction to her husband's suicide in their front yard several years ago:

    "It has been nearly six years since that February morning, but I can remember those events as clearly as though they occurred only yesterday. And in my mind's ear, I can still hear the sound of that shotgun blast, and with it the gut-wrenching realization of what had just happened. I suspect I always will." (App. 1)

IV. CONCLUSION

As the experiences of the 17 *amici* surviving family members show, many people are determined to control the dying process when faced with a debilitating terminal illness. Neither this Court nor the Attorney General can stop the terminally ill from hastening their deaths – it does happen and will continue to happen as long as human beings have free will. [10] The real

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[10] Timothy E. Quill, M.D., *A Midwife Through The Dying Process*, at 199 ("Doctors, patients, and their families are engaged in negotiated

(Cont'd)

question is *how* hastened dying for the adult terminally ill should occur: Will it be acts of violence taken alone? Will it be untrained family members compelled to assist in secrecy and fear? [11] Or will it be medically trained personnel evaluating and assisting, in the open, according to legal guidelines? [12] *Amici* urge the Court to recognize that the legal guidelines established in Oregon promote the public health and safety and serve a legitimate public interest, not only of citizens of Oregon but of the United States.

Come Death

walk toward me

in your flower-printed silk
and fine mossy velvet or
in your impeccably tailored
black suit

come in all your perfection

extending your hand
and saying your name

(Cont'd)

deaths every day in every community in the United States.") With AIDS, the number of end-of-life suicides has increased dramatically. G. Kolata, *AIDS Patients Seek Solace in Suicide But Many Risk Added Pain in Failure,* "N.Y. Times," June 14, 1994, at C1.

[11] Stephen Jamison, Ph.D., *Final Acts of Love: Families, Friends, and Assisted Dying* 169(1995) ("Until the laws change, secrecy will remain one of the most dominant features of assisted death.").

[12] *Ibid.* 5 ("This illegal assistance . . . goes on without guidelines, safeguards, psychological counseling or evaluations, required consultation with specialists, referrals to hospice, or even mandatory discussion of alternatives."). Moreover, sometimes family members are not those assisting. "In the absence of legally available aid from physicians, abuses are occurring at the hands of unregulated freelance euthanasists, illegal suppliers meeting an otherwise unmet demand." Lonny Shavelson, *A Chosen Death: The Dying Confront Assisted Suicide* 677 (1995).

draw me toward you as my close friends do
hold me elegantly still

in dance position
then waltz me away

glancing over your shoulder once

and with the smallest gesture
let them know how much
I liked to dance

(Written by Norma Davis, who died on July 16, 2001 from a self-administered dose of barbiturates prescribed under Oregon's Death with Dignity Act)

Respectfully submitted,

ROBERT A. FREE
Counsel of Record
KATRIN E. FRANK
MACDONALD HOAGUE & BAYLESS
1500 Hoge Building
705 Second Avenue
Seattle, WA 98104
(206) 622-1604

Attorneys for Amici Curiae
Surviving Family Members

(21)

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Supreme Court of the United States

ALBERTO R. GONZALES,
Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*

Respondents.

On Writ of Certiorari
To The United States Court of Appeals
For the Ninth Circuit

BRIEF OF AUTONOMY, INC. AND CASCADE AIDS PROJECT AS *AMICI CURIAE* SUPPORTING RESPONDENTS

Amy R. Sabrin*
Victoria Holstein-Childress
1440 New York Avenue, NW
Washington, DC 20005
(202) 371-7000

**Counsel of Record*
Counsel for Amici Curiae

Dated: July 21, 2005

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTERESTS OF AMICI CURIAE 1

SUMMARY OF ARGUMENT 5

ARGUMENT 6

Oregon's Death with Dignity Act strikes a legitimate balance between the interest of terminally ill people in having the option of assisted dying and the State's interest in protecting the health and welfare of its citizens 6

I. Oregon acted within its authority in passing the ODWDA, and its policy choice should be respected 8

II. Seven years' data shows that the Oregon Death with Dignity Act protects the State's legitimate interests and poses no threat to public health or welfare 10

A. The ODWDA protects all terminally ill people, including those in vulnerable groups, from abuse, coercion and "societal indifference." 11

B. The ODWDA does not foster suicide generally, or among the disabled 15

C. The ODWDA imposes strict limitations on the circumstances under which assisted dying is authorized and precludes a slide towards euthanasia 18

TABLE OF CONTENTS - Continued

D. Assisted dying under the ODWDA is consistent with the physician's role in the physician-patient relationship 22

CONCLUSION 26

TABLE OF AUTHORITIES

CASES

Barsky v. Board of Regents, 347 U.S. 442 (1954) 8

Bouvia v. Superior Court, 225 Cal. Rptr. 297 (Cal. Ct. App. 1986) 16, 22

Brecht v. Abrahamson, 507 U.S. 619 (1993) 9

Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990) 8

Griswold v. Connectict, 381 U.S. 479 (1965) 25

Hillsborough County v. Automated Medical Laboratories, 471 U.S. 707 (1985) 8

In re Marriage of Carney, 598 P.2d 36 (Cal. 1979) 3

Minnesota ex rel. Whipple v. Martinson, 256 U.S. 41 (1921) 8

New State Ice Co. v. Liebmann, 285 U.S. 262 (1932) 8

Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581 (1999) 3

Reeves, Inc. v. Stake, 447 U.S. 429 (1980) 8

Robinson v. California, 370 U.S. 660 (1962) 8

Roe v. Wade, 410 U.S. 113 (1973) 24, 25

United States v. Bass, 404 U.S. 336 (1971) 9

Vacco v. Quill, 521 U.S. 793 (1997) 6, 7

Washington v. Glucksberg, 521 U.S. 702 (1997) ..... *passim*

Whalen v. Roe, 429 U.S. 589 (1977) 8

Youngberg v. Romeo, 457 U.S. 307 (1982) 3

STATUTES

Oregon Death with Dignity Act, OR. REV. STAT. §127.800-127.995 (2005) ..... *passim*

OR. REV. STAT. § 127.800 s 1.01 (3) 12

OR. REV. STAT. § 127.805 ..... 9, 12, 13

OR. REV. STAT. § 127.810 s 3.02 (2)(a)-(b) 12

OR. REV. STAT. § 127.815 10

OR. REV. STAT. § 127.815 s 3.01 (1)(c)(E) 12

OR. REV. STAT. § 127.815 s 3.01 (1)(d) 12

OR. REV. STAT. § 127.820 12

OR. REV. STAT. § 127.825 13

OR. REV. STAT. § 127.840 12

OR. REV. STAT. § 127.845 13

OR. REV. STAT. § 127.850 13

OR. REV. STAT. § 127.855 10

OR. REV. STAT. § 127.865 10

OR. REV. STAT. § 127.885 9

OR. REV. STAT. § 127.890 13

Individuals with Disabilities Education Act, 20 U.S.C. 1400 et seq 4

Controlled Substances Act, 21U.S.C. §§ 801-971 5

The Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12111-12181 3

21 C.F.R. § 1306.04 ..... 5, 23

Termination of Life on Request and Assisted Suicide Act, Staatsblad, 2002, 165 19

OTHER AUTHORITIES

American Medical Association Council on Ethical and Judicial Affairs, Code of Medical Ethics, Opinion E-2.20 (2005) 23

American Medical Association Council on Ethical and Judicial Affairs, Code of Medical Ethics, Opinion E-2.211 (2005) 23

American Medical Association Council on Ethical and Judicial Affairs, Code of Medical Ethics, Opinion H-140.966 ¶ (4) (2005) 22

David A. Asch, *The Role of Critical Care Nurses in Euthanasia and Assisted Suicide*, 334 New Eng. J. Med. 1374 (1996) 21

Anthony L. Back, et al., *Physician-Assisted Suicide and Euthanasia in Washington State: Patient Requests and Physician Responses*, 275 JAMA 919 (1996) 20

Washington v. Glucksberg, No. 96-110, *Amici* Brief of Bioethicists 15

Amici Brief of Not Dead Yet, et al. 12, 15

Robert L. Burgdorf, Jr. & Marcia P. Burgdorf, *The Wicked Witch Is Almost Dead:* Buck v. Bell *and the Sterilization of Handicapped Persons*, 50 Temp. L.Q. 995 (1977) 4

John Carvel & Sarah Boseley, *BMA Drops Opposition to Doctor-Assisted Suicide*, Guardian (UK), July 1, 2005 22

ROBERT M. DWORKIN, LIFE'S DOMINION (1993) 16

Jody B. Gabel, *Release from Terminal Suffering? The Impact of AIDS on Medically Assisted Suicide Legislation*, 22 Fla. St. U. L. Rev. 369 (1994) 20

Linda Ganzini, et. al., *Letter to the Editor*, 343 New Eng. J. Med. 152 (2000) 14

Linda Ganzini, et al., *Oregon Physicians' Attitudes About and Experiences with End-of-Life Care Since the Passage of the Death with Dignity Act*, 285 JAMA 2363 (2001) 17, 18

Linda Ganzini, et al., *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 New Eng. J. Med. 557 (2000) 13, 14, 17

Kelly Green, Note, *Physician-Assisted Suicide and Euthanasia: Safeguarding Against the "Slippery Slope" – the Netherlands Versus the United States*, 13 Ind. Int'l & Comp. L. Rev. 639 (2003) 19

Celia Hall, *'Historic' Change as Opposition to Euthanasia Ends*, Daily Telegraph, July 1, 2005 ..... 22, 23

Hearing before the Oregon Senate Committee on HB 2954 (May 27, 1997) 9

Hearing before the Oregon House Committee on Judiciary Subcommittee on Family Law on HB 2954 (April 23, 1997) 9

Hearing before the Oregon House Committee on Judiciary Subcommittee on Family Law on Measure 16 (January 29, 1997) 9

Hearing before the Oregon Senate Committee on Judiciary on SB 491 (March 17, 1999) 9

Hearing Before the Oregon Senate Committee on Health Insurance and Bioethics on SB 1141 (April 30, 1991) 9

Bryan Hilliard, *Evaluating the Dissent in* Oregon v. Ashcroft: *Implications for the Patient-Physician Relationship and the Democratic Process*, 33 J.L. Med. & Ethics 142 (2005) 7, 23, 24

Dick Lehr, *Death & The Doctor's Hand, Increasingly, Secretly, Physicians are Helping the Incurably Ill to Die*, Boston Globe, Apr. 25, 1993 at 1 20

Roger S. Magnusson, *"Underground Euthanasia" and the Harm Minimization Debate,* 32 J. L. Med. & Ethics 486 (2004) 19, 20, 21

Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005) ..... *passim*

DAVID ORENTLICHER, M.D., MATTERS OF LIFE AND DEATH: MAKING MORAL THEORY WORK IN MEDICAL ETHICS AND THE LAW (2001) 24

Timothy E. Quill, *Dying and Decision-Making – Evolution of End of Life Options*, 350 New Eng. J. Med. 2029 (2004) 17, 18

B.A. Rich, Oregon v. Ashcroft: *The Battle Over the Soul of Medicine*, 12 Cambridge Quarterly of Health Care Ethics 313 (2003) 7

Michael Stein, *From Crippled to Disabled: The Legal Empowerment of Americans With Disabilities*, 43 Emory L.J. 245 (1994) 4

Michael Stein, *Mommy Has a Blue Wheelchair: Recognizing the Parental Rights of People With Disabilities*, 60 Brooklyn L. Rev. 1069 (1994) 4

INTERESTS OF AMICI CURIAE[1]

Amici are organizations which represent people with a wide range of disabilities who share the common belief that individuals with disabilities have the right to make choices and maintain control in all aspects of their lives. They believe that this fundamental right of self-determination applies to all significant life decisions, including what is perhaps the most uniquely personal and intimate decision of all, the decision whether to hasten impending death from a terminal disease when suffering becomes intolerable.

Thus, Amici believe that people with disabilities who are facing imminent death, and who are capable of reasoned and voluntary choice, should be permitted to hasten the end of their suffering with medications prescribed by their physicians and, thereby, to choose a death with dignity. Emphatically, Amici do not believe that responsible legislation providing this choice to terminally ill, competent adults -- including those with disabilities -- in any way poses a threat to them or diminishes their significance as valuable members of society. Accordingly, Amici believe that the people of the State of Oregon have appropriately addressed this issue by enacting the Oregon Death with Dignity Act ("ODWDA" or "the Act"), OR. REV. STAT. §§ 127.800-127.995 (2005).[2]

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[1] Pursuant to this Court's Rule 37.6, no counsel for a party authored this brief in whole or part, and no person other than amici and their counsel has made a monetary contribution for its preparation or submission. Further, the consent of the parties to the filing of this brief has been obtained and filed with the Clerk of the Court.

[2] The Oregon Death with Dignity Act was a citizen's initiative first voted into law by Oregon voters in 1994. Implementation of the Act

Amicus AUTONOMY, Inc. is a national disability rights organization incorporated and headquartered in Oregon. The Board of Directors of AUTONOMY includes some of the most prominent individuals in the disability community, including a young quadriplegic who is a counseling psychologist and editorial journalist, a noted Oregon disability rights activist, an accomplished actor in motion pictures and television who is the Associate Director of the UCLA Center for Neighborhood Knowledge, and a forensic neuropsychologist who conducts research at MIT and is an Associate Professor at the Boston University School of Medicine. All are wheelchair users who have substantial physical disabilities. AUTONOMY's mission is to protect the civil rights of people with disabilities by advocating on behalf of those in the disability community, including those with terminal illnesses, who believe in the principles of choice and self-determination.

Cascade AIDS Project ("CAP") is a non-profit organization headquartered in Oregon. CAP provides support to people who have HIV and AIDS and their families in Oregon and Southwest Washington State. CAP's efforts include educating youths and high-risk adults on HIV prevention and advocating for an effective community

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was delayed by a legal injunction, but after proceedings that included this Court's denial of a petition for certiorari, the Ninth Circuit Court of Appeals lifted the injunction in late October 1997. In November 1997, Oregon voters were asked to repeal the Act, but they declined to do so by a margin of 60% to 40%.

Since 1997, the Act has allowed mentally competent, terminally ill Oregon residents to request and obtain a lethal prescription from their physicians if they are diagnosed to have less than six months left to live. The Act contains numerous safeguards that ensure the Act will be used only for its limited intended purpose, which does not include assisting people with non-terminal conditions.

response to the AIDS epidemic. In 2004 alone, CAP taught 21,523 individuals about HIV prevention and provided direct services to 2,451 people with HIV/AIDS and their affected family members.

Both Amici organizations firmly support the continued implementation of the ODWDA. The interests of Amici reflect the interests of millions of people with disabilities, including people with terminal illnesses, throughout the country. Although the personal circumstances of people with disabilities vary substantially, they share the common interests of being able to live with dignity and to maintain control over their lives. These interests in autonomy and self-determination are the cornerstones of the disability rights movement.[3] Over time, the movement has successfully brought recognition to a broad array of rights for people with disabilities and has established a presumption in our society that disabled individuals should be empowered to make independent decisions about their lives.[4]

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[3] The terms "disability rights movement" and "independent living movement" are often used interchangeably by members of the disability community. Whether they are two separate social movements or two names for the same movement is a matter of debate. For purposes of this brief, the broader term "disability rights movement" is used to refer to both.

[4] *See, e.g., Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581, 596 (1999) (the right to be free from undue institutionalization and to live in the community); *Youngberg v. Romeo*, 457 U.S. 307, 315 (1982) (the rights to reasonably safe conditions of institutional confinement and to freedom from unreasonable bodily restraints); *In re Marriage of Carney*, 598 P.2d 36, 42 (Cal. 1979) (the right to raise a child); The Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12111-12181 (securing equal opportunities for individuals with disabilities, including the right to have access to public streets, public transportation, schools, public services, privately owned places of public accommodation, and places of

The interests of AUTONOMY and CAP in preserving the rights accorded by the ODWDA are acute. Although most members of the disability community do not have disabilities that are life-threatening in and of themselves, these individuals have the same concerns as anyone else in having the freedom to make all critical life decisions that impact their bodily integrity and dignity, including how to cross the threshold of death should they someday become terminally ill. Moreover, as discussed below, data from Oregon shows that a significant percentage of those invoking the ODWDA's protections are in the death throes of AIDS.

Amici desire a wide range of end-of-life choices should they face a terminal condition, including the right to hasten their own deaths if they determine that life during their remaining few days is no longer bearable and is depriving them of the personhood they have worked so hard to achieve. Further, they want the security of knowing that they can exercise this choice safely, effectively, legally, and in a humane and dignified manner with the professional assistance of their physicians. They reject the paternalistic view that they should be "protected" from their own end-of-life decisions and do not want their disabilities to be cited by others as justification for the wholesale denial of this right to all people with terminal illnesses.

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employment); Individuals with Disabilities Education Act, 20 U.S.C. §1400 et seq. (the right to a free and appropriate education). *See also* Michael Stein, *From Crippled to Disabled: The Legal Empowerment of Americans With Disabilities*, 43 Emory L.J. 25 (1994); Michael Stein, *Mommy Has a Blue Wheelchair: Recognizing the Parental Rights of People With Disabilities*, 60 Brooklyn L. Rev. 1069 (1994); Robert L. Burgdorf, Jr. & Marcia P. Burgdorf, *The Wicked Witch Is Almost Dead:* Buck v. Bell *and the Sterilization of Handicapped Persons*, 50 Temp. L.Q. 995 (1977).

Amici believe that the decision to hasten death is a uniquely personal, moral and religious choice, one that primarily affects the individual involved and his or her loved ones. Most importantly, it is a decision that the people of Oregon have empowered individuals to make for themselves that should not be compromised by undue federal interference.

SUMMARY OF ARGUMENT

The Oregon Death with Dignity Act was approved by the voters of Oregon to permit terminally ill people who are capable of making reasoned and voluntary decisions to end their lives in a humane and dignified manner. The Attorney General impermissibly construed the Controlled Substances Act ("CSA")[5] and its implementing regulations[6] when he issued an interpretive rule criminalizing conduct allowed by the ODWDA.

Amici contend that this decision is properly reserved to the State of Oregon in the exercise of its traditional powers to regulate the medical profession and to define criminal substantive law within its borders, and that these state powers cannot be usurped by administrative fiat. Amici further contend that the ODWDA strikes the appropriate balance between the interests of terminally ill people in the availability of assisted dying as one of several end-of-life choices, and the State's interests in protecting the health and welfare of its citizens. The ODWDA was carefully crafted to guard against potential abuses, coercion and mistake. As a result, in the seven years since the ODWDA's enactment, there has been no evidence of improper application of its

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5 21 U.S.C. §§ 801-971.

6 21 C.F.R. § 1306.04, et seq.

provisions, nor of a discriminatory effect on individuals with disabilities. Moreover, the physician's role in assisted dying under the ODWDA comports with the many and complex ethical obligations that physicians have towards their patients. As indicated by this Court and the American Medical Association, these traditional obligations include the physician's duties to respect patient autonomy, to provide comfort, to alleviate pain and suffering, and to not abandon his or her patient once it becomes apparent that the patient is terminally ill.

ARGUMENT

Oregon's Death with Dignity Act strikes a legitimate balance between the interest of terminally ill people in having the option of assisted dying and the State's interest in protecting the health and welfare of its citizens.

The ODWDA carefully balances the interest of terminally ill individuals to exercise autonomy over the most critical end-of-life decisions with the State's legitimate concerns in protecting the health and welfare of its populace. In its right-to-die cases that preceded the ODWDA, this Court identified several legitimate state interests that justify careful regulation of the decision of a mentally competent, terminally ill patient to seek a physician's aid in dying. *See Washington v. Glucksberg*, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997). In the companion cases *Glucksberg* and *Vacco*, this Court declined to recognize a fundamental, generalized right to commit suicide and upheld the constitutionality of two state laws prohibiting physician-assisted suicide after determining that the statutes at issue reasonably served legitimate state interests. *Glucksberg*, 521 U.S. at 734-35; *Vacco*, 521 U.S. at 808-09. This Court

observed that these state interests include: (1) protecting terminally ill people, including those in otherwise vulnerable groups, from abuses, coercion and "societal indifference;" (2) preventing suicide; (3) avoiding a possible slide from physician-assisted suicide to voluntary or involuntary euthanasia; and (4) protecting the ethics and integrity of the medical profession. *Glucksberg*, 521 U.S. at 728-35; *Vacco*, 521 U.S. at 808-09.

At the time *Glucksberg* and *Vacco* were decided, no U.S. jurisdiction had implemented a statute authorizing physician-assisted dying, and this Court expressed concern about the absence of empirical data to show that state regulation could adequately safeguard these state interests. *See Glucksberg*, 521 U.S. at 735; *see also id.* at 785-86 (Souter, J., concurring). This Court emphasized, however, that states are positioned ideally to grapple with nascent issues such as assisted dying and anticipated that states would do so, serving as laboratories entrusted with the challenging task of crafting appropriate protections. *See Glucksberg*, 521 U.S. at 735; *see also id.* at 737 (O'Connor, J., concurring). Since the implementation of the ODWDA in November 1997, Oregon has served as such a laboratory. Documentation of the Oregon experience shows that "the provisions of the statute have been implemented consistently 'with the predictions of its proponents and with no evidence of abuses foreshadowed in the slippery-slope characterizations of its opponents.'" Bryan Hilliard, *Evaluating the Dissent in* Oregon v. Ashcroft: *Implications for the Patient-Physician Relationship and the Democratic Process*, 33 J. L. Med. & Ethics 142, 147 (2005) (quoting B.A. Rich, Oregon v. Ashcroft: *The Battle Over the Soul of Medicine*, 12 Cambridge Quarterly of Health Care Ethics 313 (2003)).

I. Oregon acted within its authority in passing the ODWDA, and its policy choice should be respected.

Amici recognize that throughout this country, "Americans are engaged in an earnest and profound debate" concerning "the morality, legality, and practicality" of physician-assisted dying. *Glucksberg*, 521 U.S. at 735. A virtue of our federalist system, however, is that it fosters innovation by allowing for the possibility that "a single courageous State may, if its citizens choose, serve as a laboratory, and try novel social and economic experiments without risk to the rest of the country." *Reeves, Inc. v. Stake*, 447 U.S. 429, 441 (1980) (quoting *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)); *see also Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 292 (1990) (O'Connor, J., concurring). Oregon's implementation of the ODWDA typifies the role of States as laboratories.

This Court has long recognized that States' core police powers include the authority to regulate the medical profession and to define criminal substantive law within their borders. *See, e.g., Whalen v. Roe*, 429 U.S. 589, 603 n. 30 (1977) ("It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions" (citing *Robinson v. California*, 370 U.S. 660, 664-65 (1962); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954); *Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921)); *Hillsborough Cty v. Automated Medical Laboratories*, 471 U.S. 707, 715-16 (1985) (recognizing States' historic police powers to regulate health and safety and stating that these powers are presumed not to be superseded by a federal agency's health regulation promulgated "pursuant to a congressional delegation" "unless that was the clear and manifest purpose of

Congress"); *Brecht v. Abrahamson*, 507 U.S. 619, 635 (1993) (recognizing that under our principles of "comity and Federalism[,]" "[t]he States possess primary authority for defining and enforcing the criminal law"); *United States v. Bass*, 404 U.S. 336, 349-50 (1971) (same, noting further that "unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance").

Exercising this authority, Oregon has decided (by legislative codification of a voter initiative) that a mentally competent, terminally ill individual should have the freedom of choosing to hasten an end to his or her suffering with a physician's assistance, and that the individual's interest in having this option outweighs any countervailing state interests. *See* OR. REV. STAT. § 127.805. The ODWDA also reflects a policy determination that assisted dying has a medical purpose worthy of an exemption from criminal liability for physicians who comply with the Act. *See* OR. REV. STAT. § 127.885.

This difficult and sensitive policy choice is the culmination of a democratic process that considered input from Oregon's medical community, disability community, family members of terminally ill people, and bioethicists.[7] Regardless of whether one agrees with the Attorney General's view of how Oregon has chosen to regulate its

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[7] *See, e.g., Hearing before the Oregon Senate Committee on HB 2954* (May 27, 1997) (Death with Dignity Act); *Hearing before the Oregon House Committee on Judiciary Subcommittee on Family Law on HB 2954* (April 23, 1997) (same); *Hearing before the Oregon House Committee on Judiciary Subcommittee on Family Law on Measure 16* (January 29, 1997) (voter initiative approving Death with Dignity Act); *see also Hearing before the Oregon Senate Committee on Judiciary on SB 491* (March 17, 1999); *Hearing Before the Oregon Senate Committee on Health Insurance and Bioethics on SB 1141* (April 30, 1991).

medical profession and to protect physicians from criminal liability, the CSA does not authorize him to unilaterally override by administrative fiat one state's considered policy choice.

II. Seven years' data shows that the Oregon Death with Dignity Act protects the State's legitimate interests and poses no threat to public health or welfare.

The ODWDA contains detailed reporting and monitoring requirements[8] that have generated a sizeable amount of data on the circumstances and demographic characteristics of terminally ill individuals who have sought their physicians' aid in dying under the Act. This data demonstrates that there is no evidence that the statute has been used inappropriately or has resulted in any discrimination against or abuse of terminally ill individuals, including those who are members of the disability community. Indeed, conspicuously absent from Petitioners' brief is any example of an instance in which any of the dangers feared by the statute's opponents has materialized in the seven years since its inception. In particular, Petitioners assert, without further elaboration, that legalized physician-assisted dying "would pose profound risks to many

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8 The ODWDA requires that Oregon's Department of Human Services ("DHS") collect and maintain information on hastened dying under the Act. OR. REV. STAT. § 127.865. Physicians must timely notify the DHS of any lethal prescription written and document their compliance with the law. OR. REV. STAT. §§ 127.815, 127.855. The DHS, in turn, must assess the information collected and release a statistical report annually. OR. REV. STAT. § 127.865. In recent years, including 2005, the DHS has also conducted telephone interviews with all of the prescribing physicians. *See* Oregon Dep't of Human Servs., *Seventh Annual Report on Oregon's Death with Dignity Act* 10 (2005) ("Seventh Annual Report on the ODWDA").

individuals who are ill and vulnerable," Petitioners' Brief at 23, and that this end-of-life option is "fundamentally incompatible with the physician's role as healer." *Id.* at 8. Yet Petitioners do not and cannot point to any danger with specificity that could not be readily refuted by the actual experience of the State of Oregon since the implementation of the ODWDA. In particular, Oregon's experience shows that the ODWDA effectively protects each of the four state interests identified by this Court in *Glucksberg* and *Vacco*.

A. The ODWDA protects all terminally ill people, including those in vulnerable groups, from abuse, coercion and "societal indifference."

Petitioners' argument that assisted dying under the ODWDA "poses a threat to individuals who are ill and vulnerable" erroneously assumes that members of these groups are not capable of making a rational and voluntary decision to hasten their imminent and inevitable deaths. This paternalistic view is anathema to Amici and numerous members of the disability community and threatens to set back decades of legislative action and social advocacy devoted to the goal of empowering the disabled to take control over every aspect of their lives.

Moreover, the ODWDA contains numerous safeguards to ensure that a terminally ill individual's choice to hasten death with a physician's assistance is made voluntarily and free of coercion or undue influence from outside forces. The danger posed by coercion and societal indifference is that the patient will be pressured to choose a path that he or she otherwise would not choose. Opponents to assisted dying seek to do just that by substituting their own moral, philosophical or religious views for that of all patients through the elimination of this end-of-life choice.

See, e.g., Amici Brief of Not Dead Yet, et al., 1-2. The ODWDA, however, protects the decision-making autonomy of the patient by insulating him or her from these coercive forces and giving effect to the patient's true wishes, whatever course he or she chooses.

At the core of the ODWDA is the requirement that the decision to hasten death be made capably, voluntarily, and with full information. Thus the ODWDA explicitly applies only to "capable"[9] adult Oregon residents who have been diagnosed by the attending physician to be suffering from a terminal disease likely to result in death within six months, OR. REV. STAT. § 127.805, and requires two oral and one written request from the patient, OR. REV. STAT. § 127.840, the latter to be witnessed by two individuals who must attest that the patient is "capable, acting voluntarily and is not being coerced to sign the request." OR. REV. STAT. § 127.820. At least one of these witnesses cannot be a relative of the dying individual or have a stake in his or her estate. OR. REV. STAT. § 127.810 s 3.02 (2)(a)-(b). The ODWDA also requires that the physician inform the patient of the feasible alternatives to assisted dying, including "comfort care, hospice care and pain control," OR. REV. STAT. § 127.815 s 3.01 (1)(c)(E); requires that the patient be referred to a consulting physician for confirmation of the diagnosis and a determination that the patient is capable and acting voluntarily, OR. REV. STAT. § 127.815 s 3.01 (1)(d); imposes a fifteen-day waiting period between the patient's initial

[9] Under the ODWDA, "capable" "means that in the opinion of a court or in the opinion of the patient's attending physician or consulting physician, psychiatrist or psychologist, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating if those persons are available." OR. REV. STAT. § 127.800 s 1.01 (3).

request and the writing of the prescription; OR. REV. STAT. § 127.850; and permits the patient to rescind the request at any time. OR. REV. STAT. § 127.845. If either the attending or consulting physician has any concern that the patient's capacity to make the decision is impaired by a psychological or psychiatric disorder or depression, the ODWDA explicitly requires that a licensed psychologist or psychiatrist be consulted, OR. REV. STAT. § 127.825, and prohibits any medication from being prescribed until a determination regarding the presence or absence of impaired judgment is made. OR. REV. STAT. § 127.805. Finally, the statute specifically provides that "[n]o person shall qualify solely because of age or disability," OR. REV. STAT. § 127.805, and makes it a felony to coerce a patient to request medication to hasten death or to conceal or destroy a rescission of such a request. OR. REV. STAT. § 127.890.

That these safeguards meaningfully function is evidenced by data documenting Oregon's experience with the ODWDA, which shows that physicians are performing capacity assessments as required by the Act and that not all patients' requests for medication are granted.[10] *See* Oregon Dep't of Human Servs., *Seventh Annual Report on Oregon's Death with Dignity Act* 12 (2005) (*"Seventh Annual Report on the ODWDA"*); Linda Ganzini, et al., *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 New Eng. J. Med. 557, 559-60 (2000) (*"Physicians' Experiences with the ODWDA"*). Further, studies have confirmed that physicians are making ineligibility determinations based on whether a patient's judgment is

[10] One survey of Oregon physicians found that only 18% of patients who requested assisted dying under the ODWDA ultimately received a prescription. Linda Ganzini et al., *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 New Eng. J. Med. 557, 598-60 (2000).

impaired, and are not simply doling out prescriptions to anyone who asks for one. *See, e.g., Physicians' Experiences with the ODWDA,* 342 New Eng. J. Med. at 559-60. In one study surveying Oregon physicians, responses indicated that 17% of the individuals seeking medication to hasten death had "a mental disorder such as depression which impaired his/her judgment," and that none of these patients received prescriptions under the ODWDA. *Id.* The authors of that study concluded that the data did not "support the hypothesis that among patients eligible for assistance with suicide under the [ODWDA], vulnerable groups, including mentally ill patients, request suicide disproportionately or receive lethal prescriptions in place of palliative care." Linda Ganzini, et. al., *Letter to the Editor*, 343 New Eng. J. Med. 152, 152 (July 13, 2000).

Although some members of the disability community assert that people with disabilities are more vulnerable than others when assisted suicide is authorized by statute, data on the application of the ODWDA shows that this concern is unfounded. In the Oregon Department of Health's most recent study and report, the DHS observed that the demographics of patients who sought assisted dying under the ODWDA did not support opponents' fears of coercion or discrimination. *See Seventh Annual Report on the ODWDA* at 15. The study found that those requesting this end-of-life option tended to have a higher level of education than others who were terminally ill; Oregonians holding a bachelor's degree were 8.3 times as likely to request assisted dying. *Id.* at 13. The particular illness suffered was also a strong predictor of utilization of the Act; the illnesses most commonly afflicting those seeking assisted suicide were Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's Disease), HIV/AIDS, and malignant neoplasms. *Id.* at 13. Moreover, neither depression nor uncontrollable pain were strong predictors of the likelihood that a terminally ill

individual would seek physician-assisted dying. Rather, the most common reasons terminally ill patients give for choosing this end-of-life option are loss of autonomy, a decreasing ability to participate in activities that make life enjoyable, and loss of dignity. *Seventh Annual Report on the ODWDA* at 15.

B. The ODWDA does not foster suicide generally, or among the disabled.

Some disability organizations assert that Oregon's legalization of physician-assisted dying will have the cumulative impact of devaluing the lives of people with disabilities. *Amici* Brief of Not Dead Yet, et al., at 19. Implicit in this argument is the assertion that by delineating some conditions as qualifying individuals for the option of assisted suicide, the State implies that those in the eligible categories have a lower quality of life than others and that they are less valuable members of society.

The ODWDA's distinction, however, between individuals with terminal conditions and those without does not manifest the State's judgment as to the relative value or quality of life of any individual. Quality of life is a subjective valuation that belongs to the individual, not to anyone else. Under the ODWDA, only the individual facing imminent death can decide whether his or her quality of life justifies enduring whatever emotional or physical pain and suffering he or she is experiencing. By permitting that individual "to make [a] judgment about the quality of life that [he or she] may enjoy," the ODWDA "gives proper recognition to the individual's interest in choosing a final chapter that accords with [his or] her life story, rather than one that demeans [his or] her values and poisons memories of [that person]." *See Glucksberg*, 521 U.S. at 746-47 (citing and quoting *Glucksberg*, No. 96-110, *Amici* Br. of

Bioethicists at 11; RONALD M. DWORKIN, LIFE'S DOMINION 213 (1993)) (Stevens, J., concurring) (internal quotation marks and citations omitted). Whether it is in the terminally ill individual's "best interests" to choose one manner of dying rather than another depends on so much that is unique to that individual --"'the shape and character of his life[,] his own sense of his integrity and critical interests--that no uniform collective decision can possibly hope to serve everyone even decently.'" *Id.* at 747 (quoting RONALD M. DWORKIN, LIFE'S DOMINION 213 (1993)) (Stevens, J., concurring). For these reasons, the ODWDA recognizes that this critical end-of-life choice belongs to the individual alone. Neither the State nor the health care providers may decide, based on their conceptions of the individual's quality of life, whether assisted suicide is appropriate in a given case.

Nor does Oregon's implementation of the ODWDA foster suicide generally. Suicide represents in its most basic terms a choice between life and death, and is commonly perceived as a self-destructive act motivated by mental impairment -- a condition for which treatment might avoid death. In the case of a terminally ill individual, however, death is already his or her imminent fate; that individual is "faced not with the choice of whether to live, only of how to die." *Glucksberg*, 521 U.S. at 746 (Stevens, J., concurring). Terminally ill patients who choose to hasten their deaths seek to avoid a prolonged and dehumanizing process of dying. Such an individual seeks to hasten death because, in his or her view, "the quality of life during the time remaining . . . ha[s] been terribly diminished," his or her life "has been physically destroyed and its quality, dignity and purpose gone." *Bouvia v. Superior Court,* 225 Cal. Rptr. 297, 304-05 (Cal. Ct. App. 1986) (describing patient's reasons for requesting withdrawal of life support to hasten death). Under these circumstances, the choice to hasten death is more akin to the decision to refuse life-sustaining measures -- a

decision that is ethically and legally condoned -- than what is commonly perceived as "suicide."

While a terminally ill person might also suffer from depression or other mental disorder, as noted above, the ODWDA's requirements to ensure the capability of the patient requesting a lethal dosage screen out individuals who suffer from impaired judgment. The efficacy of the ODWDA's safeguards is evident in data from mental health studies which confirm that terminally ill individuals seeking assisted dying are capable of making major health care decisions and that those who receive prescriptions for lethal doses do not suffer from impaired judgment or clinical depression. *Physicians' Experiences with the ODWDA*, 342 New Eng. J. Med. at 562-63 .

Moreover, to the extent that a terminally ill individual who seeks to utilize the Act does suffer from mental incapacity or unbearable pain, the request for assisted suicide triggers intervention by the health care provider, who must assess the patient's capacity, inform him or her of alternative treatments, including palliative care, and may explore a patient's concerns and desires about end-of-life care. *See Seventh Annual Report on the ODWDA* at 17 (noting that "[o]ften once the patient's concerns have been addressed by the provider, he or she may choose not to pursue [physician-assisted suicide]" (citing Linda Ganzini et al., *Oregon Physicians' Attitudes About and Experiences with End-of-Life Care Since the Passage of the Death with Dignity Act*, 285 JAMA 2363, 2363-69 (2001)). Indeed, the notion that legalized assisted dying and the development of excellent palliative care are mutually exclusive has been largely debunked by seven years' data from Oregon on the application of the ODWDA. *See* Timothy E. Quill, *Dying and Decision-Making – Evolution of End of Life Options*, 350 New Eng. J. Med. 2029, 2030 (2004) (*"Evolution of End*

of Life Options"). In Oregon, only a small percentage of all deaths may be attributed to assisted dying under the statute (approximately 0.1 percent across seven years), *Seventh Annual Report on the ODWDA* at 16; of those who have relied upon the Act, more than three-fourths were concurrently enrolled in hospice programs. *Evolution of End of Life Options*, 350 New Eng. J. Med. at 2030; *Seventh Annual Report on the ODWDA* at 14. During 2004, all patients but one died at home; 89% were enrolled in hospice care. *Seventh Annual Report on the ODWDA* at 14.

The legalization of assisted dying in Oregon may also have encouraged doctors "to address other end-of-life care options more effectively." *Id.* In one study of Oregon physicians, the physicians reported that since the initial passage of the ODWDA in 1994, they had taken steps to increase their knowledge of palliative care for the terminally ill, to improve their ability to identify mental impairments such as depression, and to refer more patients to hospice care. *Seventh Annual Report on the ODWDA* at 17 (citing Linda Ganzini et al., *Oregon Physicians' Attitudes About and Experiences with End-of-Life Care Since the Passage of the Death with Dignity Act*, 285 JAMA 2363, 2363-69 (2001)).

C. *The ODWDA imposes strict limitations on the circumstances under which assisted dying is authorized and precludes a slide towards euthanasia.*

Opponents to physician-assisted dying point to the Netherlands as proof that the practice cannot be limited to people with terminal illnesses and that legalization of assisted dying will lead to voluntary or involuntary euthanasia. The Netherlands example, however, merely underscores the need for state regulation of assisted dying such as that afforded by the ODWDA.

Until recently, both physician-assisted suicide and euthanasia were illegal under the Dutch Criminal Code, but conditionally legalized by the Dutch Courts, which developed guidelines delineating the circumstances under which a physician would be exempt through a defense of "necessity" from criminal liability for participating in either practice. Roger S. Magnusson, *"Underground Euthanasia" and the Harm Minimization Debate*, 32 J. L. Med. & Ethics 486, 490 (2004) (*"Underground Euthanasia"*); Kelly Green, Note, *Physician-Assisted Suicide and Euthanasia: Safeguarding Against the "Slippery Slope" – the Netherlands Versus the United States*, 13 Ind. Int'l & Comp. L. Rev. 639, 665-71 (2003) (*"Safeguarding Against the Slippery Slope"*). These guidelines were adopted by the Royal Dutch Medical Association in 1984, and codified with little modification in 2002 as the Termination of Life on Request and Assisted Suicide Act ("TLRASA"). *Safeguarding Against the Slippery Slope*, 13 Ind. Int'l & Comp. L. Rev. at 667, 670.[11] In contrast to the ODWDA, the TLRASA does not require that the patient seeking hastened dying be terminally ill, does not require that the patient be mentally competent, and permits euthanasia. For a physician to be exempt from criminal liability, the TLRASA provides that (1) the patient's "suffering" must be "unbearable" "with no prospect of improvement"; (2) the patient's request must be voluntary; and (3) there must be "no reasonable alternative available to the patient." *Id.* at 670.

There is nothing to indicate that the ODWDA, which prohibits euthanasia and imposes far greater limitations on the use of assisted dying, marks the beginning of the descent

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[11] *Termination of Life on Request and Assisted Suicide Act*, Staatsblad, 2002, 165 (available in English at http://www.minbuza.nl/default.asp?CMS_TCP=tcpAsset&id=CA83[illegible]94 94B444D268938017F2330E54E) (last visited July 14, 2005).

on a slippery slope towards the acceptance of euthanasia. Indeed, there is a substantial basis to conclude that terminally ill people with disabilities are *less* vulnerable to abuses, coercion or other undue influences when assisted suicide is authorized by a statute like the ODWDA than when it is prohibited. The ODWDA ensures that only people with the requisite training may assist a terminally ill patient in dying, that the patient is mentally competent to make the decision, and that the decision is made voluntarily and with full information. The fact remains that in jurisdictions that do not permit physician-assisted suicide, including jurisdictions where the practice is outlawed, the practice persists, with no procedural safeguards in place. *See Underground Euthanasia*, 32 J. L. Med. & Ethics at 486 (observing that the empirical evidence that doctors participate in assisted suicide and euthanasia despite prohibitions is beyond serious dispute); Jody B. Gabel, *Release from Terminal Suffering? The Impact of AIDS on Medically Assisted Suicide Legislation*, 22 Fla. St. U. L. Rev. 369, 372-73 (1994); Dick Lehr, *Death & The Doctor's Hand, Increasingly, Secretly, Physicians are Helping the Incurably Ill to Die*, Boston Globe, Apr. 25, 1993 at 1.

The very fact that covert assisted suicide and euthanasia is occurring in prohibitionist states at rates that rival those of the Netherlands,[12] necessarily undermines any slippery slope characterization of legalized assisted dying: "that if [assisted suicide] is legalized, bad things will start to happen. The fact is, harmful, unsafe things are already happening." *Underground Euthanasia*, 32 J. L. Med. & Ethics at 492. Indeed, a nationwide study of 1,902 U.S.

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12 Anthony L. Back, et al., *Physician-Assisted Suicide and Euthanasia in Washington State: Patient Requests and Physician Responses*, 275 JAMA 919, 924 (1996); *"Underground Euthanasia"*, 32 J. L. Med. & Ethics at 490.

physicians found that, notwithstanding the current legal restraints, 8 percent of physicians surveyed had participated in assisted suicide or euthanasia, with 3.3 percent admitting that they had written at least "one lethal prescription" and 4.7 percent admitting that they had administered at least one lethal injection. *Underground Euthanasia*, 32 J. L. Med. & Ethics at 486.

Bans on assisted suicide and euthanasia also have not prevented non-physicians from coming to the aid of the dying. One study surveyed 1,139 critical care nurses in the United States, of which 852 (71 percent) practiced exclusively in intensive care units for adults. David A. Asch, *The Role of Critical Care Nurses in Euthanasia and Assisted Suicide*, 334 New Eng. J. Med. 1374, 1374-75 (1996). Of the 852 nurses, 141 (17 percent) reported requests from patients or family members for euthanasia or assisted dying; of the 17 percent asked, 129 (16 percent) complied. *Id.* at 1374-79. An additional four percent admitted they had facilitated a terminally ill patient's death by pretending to provide life-sustaining treatment ordered by a physician. *Id.* According to one expert, covert assisted dying and voluntary euthanasia "has spawned a culture of deception," "encompass[ing] the methods used to procure euthanasia drugs, the planning of the death itself, and the disposal of the body and associated paperwork." *Underground Euthanasia*, 32 J. L. Med. & Ethics at 488. In many instances, patients die without having been evaluated for depression or impaired judgment, without adequate palliative care or counseling, and without the assessment of specialists as to the patient's diagnosis, prognosis, and available treatment alternatives. *Id.*

The question thus becomes not whether the option of assisted dying should be available or not, but whether it

should be regulated to prevent the abuses that occur in the absence of regulation.

D. Assisted dying under the ODWDA is consistent with the physician's role in the physician-patient relationship.

Petitioners contend that physician-assisted suicide is "fundamentally incompatible with the physician's role as healer."[13] Petitioners' Brief at 8. This argument, and the Attorney General's Directive that assisting suicide is not a "legitimate medical purpose" within the meaning of the CSA's implementing regulations, 21 C.F.R. § 1306.04, are based on a conception of the physician-patient relationship that minimizes or disregards the many and complex obligations that physicians have towards their patients. *See* Bryan Hilliard, *Evaluating the Dissent in* Oregon v. Ashcroft: *Implications for the Patient-Physician Relationship and the Democratic Process*, 33 J. L. Med. & Ethics 142, 147 (2005) ("*Evaluating the Dissent in* Oregon v. Ashcroft").

The Attorney General's Directive criminalizing physician-assisted suicide conflicts with the traditional ethical obligations of the medical profession to respect patient autonomy, to provide comfort, and to alleviate pain and suffering. *See* American Medical Association Council on Ethical and Judicial Affairs, Code of Medical Ethics, Opinion E-2.20 (2005) ("AMA Code") (instructing that where the physician's duty to "sustain life" conflicts with his or her duty to "relieve suffering," "the preferences of the patient shall prevail"); *id.* ("Physicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care."). Moreover, physicians have an obligation not to abandon patients "once it is determined that cure is impossible." AMA Code E-2.211 (2005). In its opinion on physician-assisted suicide, the American Medical Association ("AMA") instructs that "[p]atients near the end of life must continue to receive emotional support, comfort care, adequate pain control, respect for patient autonomy, and good communication." *Id.*

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[13] This view, which is shared by the American Medical Association, stems from the Hippocratic Oath's provision that "I will give no deadly treatment to anyone if asked . . ." *But see Bouvia v. Superior Court*, 225 Cal. Rptr. 297, 308 (1986) (reasoning that "[s]urely, adherence to the oath would yet admit of a reasonable balancing between the doctor's obligation to alleviate suffering and his obligation to preserve life"). The medical profession has in fact accommodated deviations from the oath in the past, *see id.* (noting that the oath also provides that "I will not give a woman an instrument to produce abortion"), and the AMA has left open the possibility that it will likewise change its position on assisted suicide. *See* AMA Code H-140.966 ¶ (4) (2005) (acknowledging in its statement on euthanasia and assisted suicide that "[i]n certain carefully defined circumstances, it would be humane to recognize that death is certain and suffering is great," but "more careful examination of the issue is necessary" and that "the societal risks of involving physicians in medical interventions to cause patients' deaths is too great to condone euthanasia or physician-assisted suicide *at this time*") (emphasis added). Significantly, the British Medical Association ("BMA") recently did exactly that and departed from its longstanding opposition to physician-assisted suicide. Celia Hall, *'Historic' Change as Opposition to Euthanasia Ends*, Daily Telegraph, July 1, 2005 ("*'Historic' Change*"), *available at* 2005 WLNR 10348879; John Carvel & Sarah Boseley, *BMA Drops Opposition to Doctor-Assisted Suicide*, Guardian (UK), July 1, 2005 ("*BMA Drops Opposition*"), *available at* 2005 WLNR 10318566. As of late June 2005, the BMA has officially taken a "neutral position" on the issue, meaning that it would not object to the passage of legislation allowing physician-assisted suicide. *BMA Drops Opposition*, Guardian (UK), July 1, 2005. According to Dr. Evan Harris, the Member of Parliament who urged the BMA to change its policy, whether assisted dying should be permitted "is now a matter for Parliament to decide, and the role of the medical profession is to press for the necessary safeguards, not to oppose an overdue move." *'Historic' Change*, Daily Telegraph, July 1, 2005.

As one commentator has observed, physicians who participate in assisted dying believe that they are adhering to their obligation to aid and comfort their patients. DAVID ORENTLICHER, M.D., MATTERS OF LIFE AND DEATH: MAKING MORAL THEORY WORK IN MEDICAL ETHICS AND THE LAW 42 (2001) ("When a patient and a physician have gone together through a long and arduous battle with disease, and the patient concludes that suicide is now the best option, the physician may not want to abandon the patient and insist that the patient go forward without the physician by her side"). This view reflects the belief shared by proponents and opponents to assisted suicide that the use of controlled substances provides the least painful and most dignified method of hastening one's death. *See Evaluating the Dissent in* Oregon v. Ashcroft, 33 J. L. Med. & Ethics at 142. Indeed, during the period when death is imminent and suffering becomes intolerable, the decision to hasten imminent death is most analogous "to decisions that are generally accepted as proper instances of exercising autonomy over one's own body, instances recognized under the Constitution and the State's own law in which a physician's assistance is accepted as falling within the traditional ethical norm of professional conduct." *See Glucksberg*, 521 U.S. at 779-80 (Souter, J., concurring) (noting that such instances include the administration of heavy dosages of pain medication, even if such unintentionally hastens death, the withdrawal or withholding of life-sustaining medical treatment, and the practice of terminal sedation).

Indeed, this Court implicitly has rejected the type of one-dimensional understanding of the physician-patient relationship advanced by Petitioners. *See Roe v. Wade*, 410 U.S. 113, 153 (1973) (declining to limit the physician's participation to curative measures and recognizing the physician's obligation to provide and the patient's right to

receive counsel and care in the abortion context); *see also Glucksberg*, 521 U.S at 779 (Souter, J., concurring). In his concurring opinion in *Glucksberg*, Justice Souter expressed concern that terminal sedation might be the only option available to terminally ill patients seeking to hasten an end to their suffering. *Glucksberg*, 521 U.S at 779 (Souter, J., concurring). Recognizing that "[t]here can be no stronger claim to a physician's assistance than at the time when death is imminent," *id.* at 781, Justice Souter observed that this Court's abortion cases illustrate a broader view of the physician's role that would encompass assisted dying. *See Glucksberg*, 521 U.S at 779 (Souter, J., concurring). As Justice Souter explained, this Court has recognized that "the good physician is not just a mechanic of the human body whose services have no bearing on a person's moral choices, but one who does more than treat symptoms, one who ministers to the patient." *Glucksberg*, 521 U.S at 779 (Souter, J., concurring) (citing *Roe*, 410 U.S. at 153; *Griswold v. Connecticut*, 381 U.S. 479, 482 (196[illegible])). Refuting the notion that the physician's role is limited to that of "healer," Justice Souter further explained:

> This idea of the physician as serving the whole person is a source of high value traditionally placed on the medical relationship. Its value is surely as apparent here as the abortion cases, for just as the decision about abortion is not directed to correcting some pathology, so the decision in which a dying patient seeks help is not so limited. The patients here sought not only an end to pain (which they might have had although at the price of stupor) but an end to their short remaining lives with a dignity they believed would be denied them by powerful pain medication, as well as by their consciousness of

dependency and helplessness as they approached death.[14]

Regardless of whether one agrees with the Attorney General's view of the physician-patient relationship, the CSA does not authorize him to impose his definition of the physician's role upon states, physicians and patients through administrative fiat. Amici acknowledge that the question whether physician-assisted suicide is part of the legitimate practice of medicine is the subject of debate, but the Attorney General impermissibly seeks to delineate the contours of the physician-patient relationship in a manner that is contrary to congressional intent and that disregards the multiple role obligations of the medical profession.

CONCLUSION

For decades, individuals with disabilities have had to defend their right to make choices and maintain control over all aspects of their lives. Amici believe that this right to autonomy and self-determination applies with no less force to the most uniquely personal, moral and religious choice of all -- the choice of whether to hasten impending death from a terminal condition. Most importantly, it is a choice that Oregon in its considered policy determination has empowered all capable, terminally ill adults, including those with disabilities, to make for themselves. This policy determination cannot be superseded by the unilateral action of a federal agency where, as here, Congress did not clearly convey its intent to disrupt the delicate federal-state balance. For all the foregoing reasons, Amici respectfully submit that the decision of the Court of Appeals should be affirmed.

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[14] *Glucksberg*, 521 U.S. at 779 (Souter, J., concurring).

Respectfully submitted,

Amy R. Sabrin*
Victoria Holstein-Childress
1440 New York Avenue, NW
Washington, DC 20005
(202) 371-7000

**Counsel of Record*

Counsel for Amici Curiae

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No. 04-623

In the Supreme Court of the United States

Alberto R. Gonzales, Attorney General, *et al.*,
Petitioners

v.

State of Oregon *et al.*,
Respondents

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF FOR THE RESPONDENTS
filed by Peter A. Rasmussen, M.D.
and David M. Hochhalter

ELI D. STUTSMAN
Counsel of Record
621 SW Morrison
Thirteenth Floor
Portland, OR 97205
(503) 274-4048

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

STATEMENT OF THE CASE 1

The proceedings below 1

The Attorney General's enforcement directive 4

Standing to litigate 6

The State of Oregon is leading a national debate 7

SUMMARY OF ARGUMENT 8

ARGUMENT 11

I. The Attorney General's enforcement directive violates the plain language of the Controlled Substances Act, oversteps the bounds of the Attorney General's statutory authority, and contravenes Congress' express legislative intent 11

A. Medical Practice under the Oregon Death With

Dignity Act establishes the "course of professional practice" 14

B. Criminal proceedings under the Controlled Substances Act; drug trafficking, drug diversion, and the "course of professional practice" 20

C. Administrative proceedings under the Controlled Substances Act; revocations, denials, and the "public interest" 29

D. The Congressional record establishes that the Controlled Substances Act is an anti-drug law-enforcement statute, not a medical practices act 34

II. The States, not the Attorney General acting through the Controlled Substances Act, regulate medicine 41

III. The power to regulate commerce between the States does not authorize federal usurpation of medical practice in the States, or the manner in which Oregonians die 47

CONCLUSION 50

TABLE OF AUTHORITIES

Page

Cases Cited

Alden v. Maine,
527 U.S. 706 (1999) 45, 49

Arthur Andersen, LLP v. United States,
125 S.Ct. 2129 (2005) 21, 22

Barsky v. Board of Regents,
347 U.S. 442 (1953) 10, 44

Circuit City Stores, Inc. v. Adams,
532 U.S. 105 (2001) 32

Gibbon v. Ogden,
9 Wheat. 1 (1824) 47

Gonzales v. Raich,
125 S. Ct. 2195 (2005) 12, 15, 49

Gregory v. Ashcroft,
501 U.S. 452 (1991) 45

Estate of Hagedorn ex rel. Hagedorn v. Peterson,
690 N.W.2d 84 (Iowa, 2004) 43

Humphreys v. DEA,
96 F.3d 658 (3rd Cir. 1996) 28

Jinkins v. Lee,
807 N.E.2d 411 (Ill., 2004) 43

Labor Board v. Jones & Laughlin,
301 U.S. 1 (1937) 48

LaFramboise v. Thompson,
329 F.Supp.2d 1054 (D.N.D., 2004) 43

Liggett Co. v. Baldridge,
278 U.S. 105 (1928) 44

Linder v. United States,
268 U.S. 5 (1924) 10, 44

Printz v. United States,
521 U.S. 898 (1997) 45

Raygor v. Regents of University of Minnesota,
543 U.S. 533 (2002) 46

Rush Prudential HMO, Inc. v. Moran,
536 U.S. 355 (2002) 10, 44

Semler v. Dental Examiners,
294 U.S. 608 (1934) 44

Sheeley v. Memorial Hosp.,
710 A.2d. 161 (R.I., 1998) 42

Sturges v. Crowninshield,
4 Wheat. 122 (1819) 50

United States v. Aguilar,
515 U.S. 593 (1995) 22

United States v. Brower,
336 F.3d 274 (4th Cir. 2003) 21

United States v. Collier,
478 F.2d 268 (5th Cir. 1973) 26, 28

United States v. King,
345 F.3d 149 (2nd Cir. 2003) 21

United States v. Lopez,
514 U.S. 549 (1995) 47, 48, 49

United States v. Moore,
423 U.S. 122 (1975) ..... *passim*

United States v. Morrison,
529 U.S. 598 (2000) 47, 50

United States v. Oregon Med. Soc.,
343 U.S. 326 (1951) 44

United States v. Rosen,
582 F.2d 1032 (5th Cir. 1978) 9, 26, 27, 28

United States v. Rosenberg,
515 F.2d 190 (9th Cir. 1975) 9, 28

U.S. Term Limits, Inc. v. Thornton,
514 U.S. 779 (1995) 50

Washington v. Glucksberg,
521 U.S. 702 (1997) 7

Adjudicated Cases Cited

Wesley G. Harline, M.D.,
65 Fed. Reg. 5665 (2000) 29

William J. Roth, M.D.,
60 Fed. Reg. 62262 (1995) 29

Paul W. Saxton, D.O.,
64 Fed. Reg. 25073 (1999) 29

William F. Skinner, M.D.,
60 Fed. Reg. 62887 (1995) 29

Federal Statutes

5 U.S.C. § 706(2)(C), (D) 3

21 U.S.C. §§ 801-904 2

21 U.S.C. §§ 801-950 ..... *passim*

21 U.S.C. §§ 801(1)-(6) 12

21 U.S.C. § 802(21) 9, 14, 15, 21, 28

21 U.S.C. § 822(a)(2) 21

21 U.S.C. § 822(b) 21

21 U.S.C. § 823 31

21 U.S.C. § 823(f) 8, 30, 31, 33, 47, 48, 50

21 U.S.C. § 823(f)(1),(3)&(4) 31

21 U.S.C. § 823(f)(1)-(5) 30, 31

21 U.S.C. § 823(f)(2)&(5) 31

21 U.S.C. § 823(f)(5) 32

21 U.S.C. § 824(a) 31

21 U.S.C. § 824(a)(4) 4, 31

21 U.S.C. § 829 23

21 U.S.C. § 829(a) & (b) 21

21 U.S.C. § 841 24

21 U.S.C. § 841(a) 21

21 U.S.C. § 841(a)(1) 12

21 U.S.C. § 844(a) 12

21 U.S.C. § 903 ..... 45, 46

Controlled Dangerous Substances Act 37

Crime Control Act of 1990 48

Dangerous Drug Diversion Control Act of 1984 ..... 30, 38, 40

Indian Child Welfare Act 13

National Motor Vehicle Theft Act 13

Revenue Act of 1932 13

Security Exchange Act of 1934 13

Federal Rules

21 CFR § 1306.04 ..... 4, 8, 9, 13, 14, 28, 47, 48, 50

21 CFR § 1306.04(a) 23

Supreme Court Rule 24(2) 1

State Statutes

Or. Rev. Stat. §§ 127.800 to 127.897 ..... *passim*

Or. Rev. Stat. § 127.815 ..... 18, 20

Or. Rev. Stat. § 127.815(1)(k) 16

Or. Rev. Stat. § 127.815(1)(L)(A) 16, 18

Or. Rev. Stat. § 127.855(1)-(7) 5

Or. Rev. Stat. § 127.865(3) 5

Or. Rev. Stat. § 127.880 15

Or. Rev. Stat. § 163.125 ..... 7, 14

Or. Rev. Stat. § 677.095(1) 44

Other Authorities

116 Cong. Rec. 973 (1970) 34

116 Cong. Rec. 976 (1970) 34

116 Cong. Rec. 978 (1970) 35

116 Cong. Rec. 996 (1970) 35, 36

116 Cong. Rec. 33,315 (1970) 37

116 Cong. Rec. 33,656 (1970) 37

116 Cong. Rec. 35,051-52 (1970) 38

130 Cong. Rec. 25,846 (1984) 38

130 Cong. Rec. 25,848 (1984) 39

130 Cong. Rec. 25,849 (1984) 40

130 Cong. Rec. 25,851 (1984) 40

James O. Pearson, Jr., J.D., *Modern Status of "Locality Rule" in Malpractice Action Against Physician Who is Not a Specialist*, 99 A.L.R.3d 1133 (1980) (updated through 2004) .. 43

2A N. Singer, *Sutherland on Statutes and Statutory Construction*, § 47.17 (1991) 32

STATEMENT OF THE CASE[1]

One day after the State of Oregon filed suit, practitioner-respondents Peter A. Rasmussen, M.D., and David M. Hochhalter, a physician and a pharmacist, ("practitioners") filed a complaint in intervention suing United States Attorney General John Ashcroft, *et al.*, to prevent criminal and civil enforcement proceedings against them for having prescribed and dispensed schedule II controlled substances under the Oregon Death With Dignity Act, Or. Rev. Stat. 127.800 *et seq*.

The proceedings below

On November 8, 2001, the district court granted all respondents' request for a temporary restraining order, enjoining the Attorney General from enforcing the Controlled Substances Act (CSA) against Oregon physicians and pharmacists practicing in accord with the Oregon Death With Dignity Act.

On November 20, 2001, at the conclusion of the preliminary injunction hearing, the parties agreed to extend the temporary restraining order in lieu of a court ruling on respondents' motion for a preliminary injunction.

On April 17, 2002, the district court granted summary judgment in favor of all respondents and permanently enjoined the Attorney General from enforcing, applying, or otherwise giving any legal effect to his enforcement directive. See Pet. App. 97a. The district court reasoned as follows:

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[1] In accord with Supreme Court Rule 24(2), practitioner-respondents supplement petitioners' statement.

> I conclude that Congress did not intend the CSA to override a state's decisions concerning what constitutes legitimate medical practice, at least in the absence of an express federal law prohibiting that practice. Similarly, I conclude that Congress never intended, through the CSA or through any other current federal law, to grant blanket authority to the Attorney General or the DEA to define, as a matter of federal policy, what constitutes the legitimate practice of medicine.

Pet. App. 77a-78a.

On May 26, 2004, the Ninth Circuit Court of Appeals affirmed, finding the enforcement directive unenforceable:

> A doctor, a pharmacist, several terminally ill patients, and the State of Oregon challenge an interpretive rule issued by Attorney General John Ashcroft which declares that physician assisted suicide violates the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. §§ 801-904. This so-called "Ashcroft Directive," published at 66 Fed.Reg. 56,607, criminalizes conduct specifically authorized by Oregon's Death With Dignity Act, Or. Rev. Stat. § 127.800-127.897. We hold that the Ashcroft Directive is unlawful and unenforceable because it violates the

> plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority. *See* 5 U.S.C. § 706(2)(C), (D). * * * .

Pet. App. 2a; see also *id.* at 9a:

> We hold that the Attorney General lacked Congress' requisite authorization. The Ashcroft Directive violates the "clear statement" rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

The Ninth Circuit Court of Appeals concluded its analysis as follows:

> In sum, the CSA was enacted to combat drug abuse. To the extent that it authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of Health and Human Services, not to the Attorney General. The Attorney General's unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds the scope of his authority under federal law. We therefore hold that the

> Ashcroft Directive is invalid and may not be enforced.

Id. at 24a.

The Attorney General's enforcement directive

In a two page enforcement directive (Pet. App. 100a-105a) released November 6, 2001, the Attorney General determined the following:

> 1. *Determination on Use of Federally Controlled Substances to Assist Suicide.* For the reasons set forth in the OLC Opinion, *I hereby determine that assisting suicide is not a "legitimate medical purpose"* within the meaning of 21 CFR § 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA. Such conduct by a physician registered to dispense controlled substances may "render his registration * * * *inconsistent with the public interest*" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). This conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted.

Pet. App. 102a (emphasis added). The Attorney General directed that his findings be immediately enforced upon publication:

> I hereby direct the DEA, *effective upon publication of this memorandum in the Federal Register*, to enforce and apply this determination, notwithstanding anything to the contrary in the June 5, 1998, Attorney General [Janet Reno]'s letter.

Pet. App. 102a-103a (emphasis added). Consequently, but for the district court's November 8, 2001 restraining order, the enforcement directive would have gone into effect upon publication in the Federal Register on November 9, 2001.

The Attorney General's enforcement threat was limited to Oregon practitioners. *Id.* at 103a (there is "no change in the current standards and practices of the DEA in any State other than Oregon"). The Attorney General further dictated an enforcement strategy. The Oregon Death With Dignity Act[2] imposes statutory record keeping requirements upon practitioners[3] and public reporting requirements upon the Oregon Department of Human Services.[4] The Attorney

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[2] The full text of the Oregon Death With Dignity Act is appended to the Practitioners' Brief in Opposition, 1a-20a ("Practitioners' App.").

[3] See Practitioners' App. 9a-10a (Or. Rev. Stat. § 127.855(1)-(7) (medical record documentation requirements)).

[4] See Practitioners' App. 11a (Or. Rev. Stat. § 127.865(3) (reporting requirements)).

General concluded that those publicly held records should facilitate enforcement proceedings:

> 4. Enforcement in Oregon. * * * . Those records should contain the information necessary to determine whether those holding DEA registrations who assist suicides *in accordance with Oregon law* are prescribing federally controlled substances for that purpose *in violation of the CSA* * * * .

Pet. App. 103a-104a (emphasis added). The Attorney General determined that the DEA had the authority to obtain those records, *id.* at 104a, and concluded his enforcement directive with a distribution instruction in Oregon:

> 5. Distribution. Please ensure that this Memorandum and the OLC opinion on which it is based are promptly distributed to appropriate DEA personnel, *especially those with authority over the enforcement of the CSA in Oregon.*

Id. (emphasis added).

Standing to litigate

Respondents Rasmussen and Hochhalter have standing to challenge the Attorney General's enforcement directive because both have practiced medicine in Oregon and, when appropriate, have prescribed and dispensed controlled

substances under the CSA and Oregon's Death With Dignity Act. See Practitioners' App. 22a-32a (practitioners' affidavits). As such, both are among the primary targets of the Attorney General's enforcement directive and, but for injunctive relief, both are subject to administrative and criminal sanctions pursuant to the Attorney General's enforcement directive.

The State of Oregon is leading a national debate

In *Washington v. Glucksberg*, 521 U.S. 702 (1997), this Court declined to recognize a "generalized" constitutional right to a physician-assisted death.[5] Central to that result was the court's observation that, "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Id.* at 719. "Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735. The issue is one that "is entrusted to the 'laboratory' of the States." *Id.* at 737 (O'Connor, J., concurring, joined by Justices Ginsberg and Breyer); see also *id.* at 738 (Stevens, J., concurring) and at 788 (Souter, J., concurring).

Oregon has been at the forefront of this debate. The Oregon Death With Dignity Act was adopted by the people of Oregon at the November 8, 1994 election. Three years later, on November 7, 1997, the people of Oregon decisively rejected, by a margin of 60 percent to 40 percent, a ballot

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[5] Respondents use the term "assisted death" in recognition that "assisted suicide" is still a crime in Oregon. See Or. Rev. Stat. § 163.125 (second degree manslaughter), appended, Practitioners' App. 21a. It is preferable not to use the language of a crime when referring to non-criminal activity.

measure to repeal the Oregon Death With Dignity Act. Two years after that, on June 30, 1999, Governor John Kitzhaber, M.D., signed into law Senate Bill 491, amending the Oregon Death With Dignity Act. As such, the Oregon Death With Dignity Act is a duly enacted state law, twice approved by Oregon voters, subsequently amended by the state legislature and signed into law by Oregon's governor, himself a physician. It is a rare law that has been so thoroughly tested and approved by a state's democratic process.

SUMMARY OF ARGUMENT

Schedule I banned substances are not used under the Oregon Death With Dignity Act, and the Attorney General does not allege that Oregon practitioners are diverting lawful Schedule II substances out of the "closed" system of regulation, from legitimate to illicit channels, or that Oregon practitioners are unlicensed, unregistered, or otherwise unqualified to possess, prescribe, or dispense controlled substances. Consequently, this case has nothing to do with illicit drug use, drug trafficking, or drug diversion.

The Attorney General's interpretative ruling is simply an enforcement directive giving effect to national medical policy, regulating the practice of medicine, and specifically targeting the State of Oregon and DEA registrants practicing under the Oregon Death With Dignity Act. To accomplish his purpose, the Attorney General relies upon a 1984 amendment to the CSA (21 U.S.C. § 823(f)--"public interest") and an agency rule (21 C.F.R. § 1306.04--"legitimate medical purpose"), neither of which empower the Attorney General to regulate the practice of medicine or to impose his preferred medical policies upon the State of Oregon.

The Attorney General substitutes the language of the rule, 21 C.F.R. § 1306.04 ("legitimate medical purpose") for the language of the statute, 21 U.S.C. § 802(21) ("course of professional practice"), and then infuses the word "legitimate" with a subjective, value-laden meaning unsupported by the legislative record. Congress, however, never intended that the Attorney General would pass judgment on the "legitimacy" of medical policy in the States in the absence of illicit drug use, drug trafficking and drug diversion.

The Attorney General also removes his authorities from their proper context. Unlike the drug-dealing physicians in the *Rosenberg*, *Moore*, and *Rosen* cases, for example, there is no allegation by the DOJ or the DEA that physicians practicing under the Oregon Death With Dignity Act are diverting drugs from legitimate to illicit channels. Rather, both the DOJ and the DEA concede that Oregon practitioners are practicing in accordance with Oregon law, and that the drugs are used for their intended purpose within the closed system of regulation. Consequently, there is no illicit drug use, no drug trafficking, and no drug diversion. No law is broken. No crime is committed. Not even the community standard of care is violated.

The express language of the CSA, the case law interpreting the CSA, and the legislative record in support of the CSA, all make clear that the Attorney General's proper role is to regulate the manufacture, dispensing and distribution of controlled substances to prevent illicit drug use, trafficking, and diversion. Aside from encouraging drug education, research, and rehabilitation, the CSA serves a law-enforcement purpose and no other purpose. Nothing contained in the CSA gives the Attorney General direct control over the practice of medicine in the States, nor could

it. See, *e.g.*, *Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government"); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1953) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power"); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (determination of medical necessity and standards of reasonable care are "quintessentially state-law" determinations).

Not only must the Attorney General persuade this Court that his interpretation of the CSA is correct, he must further demonstrate that it was the intent of Congress to alter the state/federal framework--in this case, by permitting federal encroachment into the practice of medicine, an area of traditional State concern. He fails on both counts.

The Attorney General's bias was exposed in the Ninth Circuit Court of Appeals below when he framed the issue as "healing, not killing." Appellants' Brief, 11. Once the Attorney General's argument is exposed for what it is--a policy disagreement with the State of Oregon over the practice of medicine, and not a disagreement over the enforcement of the CSA to prevent illicit drug use, drug trafficking, or drug diversion--the inquiry should be over.

Finally, the power to regulate commerce between the States does not permit federal control over the manner in which Oregonians die, the choices they possess when facing death, the scope of state criminal laws prohibiting assisted suicide, or state health-care laws permitting a physician-assisted death.

ARGUMENT

I. The Attorney General's enforcement directive violates the plain language of the Controlled Substances Act, oversteps the bounds of the Attorney General's statutory authority, and contravenes Congress' express legislative intent.

The Controlled Substances Act, 21 U.S.C. §§ 801-950, controls certain delineated substances by first classifying them and then setting restrictions on each class of substance. These restrictions apply to the manufacture, distribution, sale, possession, and use of such substances. The classifications range from schedule I substances, which have no recognized medical use and are therefore banned except in very limited research contexts, to schedule II, III, IV and V substances, which have recognized uses and can be manufactured, distributed, possessed and used, subject to the restrictions of the CSA. As this Court recently explained:

> the CSA, repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic *in illicit drugs. The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic* in controlled substances. * * * Congress was particularly concerned with *the need to prevent the diversion of drugs from legitimate to illicit channels.* * * * .

> To effectuate these goals, Congress devised *a closed regulatory system* making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§ 841(a)(1), 844(a).

Gonzales v. Raich, 125 S.Ct. 2195, 2203 (2005) (emphasis added, footnotes omitted); citing 21 U.S.C. §§ 801(1)-(6) (Congressional findings); *United States v. Moore*, 423 U.S. 122, 135 (1975); H.R. Rep. No. 91-1444, pt. 2, p. 22 (1970).

In *Gonzales v. Raich*, this Court very recently upheld the power of Congress to classify marijuana as a schedule I banned substance. Unlike in *Raich*, however, there is no allegation in the instant case that a schedule I banned substance is being used under the Oregon Death With Dignity Act.[6] Nor does the Attorney General allege that Oregon practitioners are diverting lawful Schedule II substances out of the "closed" system of regulation, from legitimate to illicit channels, or that Oregon practitioners are unlicensed, unregistered, or otherwise unqualified to possess, prescribe, or dispense controlled substances.

The Attorney General instead argues that although "schedule II substances have *other* generally accepted medical

[6] The Attorney General readily concedes that schedule II substances are used under Oregon's unique law. See Pet. App. 132a, n.25; see also Pet. Br. 29, n.11 ("the three drugs that have been dispensed pursuant to the DWDA are secobarbital, pentobarbital, and amobarbital, all of which are schedule II depressants").

uses in treatment, deliberately assisting a person to commit suicide is not one of them." Pet. Br. 30 (italics in original, underscore added). In support of his position, the Attorney General invokes what he describes as a "broad consensus" evidenced by "centuries of almost uniform opposition" and "the law of 49 of the 50 States." Pet. Br. 18.

The Attorney General locates in the CSA each use of the words "legitimate" and "treatment" and concludes that he is empowered under the CSA to judge whether a specific medical practice is legitimate, Pet. Br. 18-24, even in the absence of illicit channels of distribution, drug trafficking, or drug diversion, and regardless of state law and the medical standard of care.

The Attorney General cites four authorities (Pet. Br. 25-26) in support of his "national standards" argument (Pet. Br. 26-37) that when Congress enacted the CSA, it "believed [that] *medical judgments* could and should be made *on the national level*." Pet. Br. 27 (emphasis added). The Attorney General relies upon cases that interpret "maturity," as used in the Security Exchange Act of 1934; "stolen," as used in the National Motor Vehicle Theft Act; "future interests," as used in the Revenue Act of 1932; and "domicile," as used in the Indian Child Welfare Act. Pet. Br. 25. In none of these cases, however, did a federal agency seek through application of an agency rule (21 C.F.R. § 1306.04--"legitimate medical purpose") to so drastically alter the meaning of a statute, or to expand a federal agency's power to regulate medicine, an area of traditional state concern.

Although Congress provided immunity from criminal prosecution to physicians and pharmacists who prescribe, possess, and dispense controlled substances "in the course of

professional practice" (21 U.S.C. § 802(21)), the Attorney General instead relies upon a fragment of an agency rule, *i.e.*, that pursuant to 21 C.F.R. § 1306.04, a prescription for a controlled substance must be issued for a "*legitimate medical purpose*."[7] See Pet. App. 102a (enforcement directive). The Attorney General places a particularly strong emphasis on the word "legitimate" and, by the time he is through with his interpretation of the rule, any deference to the practice of medicine under the "course of professional practice" standard, or to the States to regulate medicine, is subsumed by the Attorney General's inquiry into the legitimacy of Oregon's medical policy. Although he fails to allege drug trafficking, drug diversion, or the use of schedule I banned substances, the Attorney General has nonetheless construed an agency rule so as to empower the DEA to investigate, prosecute and convict both respondents for what amounts to a violation of the national medical policy he espouses in his enforcement directive.

A. Medical practice under the Oregon Death With Dignity Act establishes the "course of professional practice."

When the State of Oregon adopted its Death With Dignity Act in 1994, it created a narrow exception to its penal code prohibiting assisted suicide[8] and also codified a new

[7] 21 C.F.R. § 1306.04 provides in relevant part, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice * * * ."

[8] See Or. Rev. Stat. § 163.125 (second degree manslaughter), appended, Practitioners' App. 21a.

standard of care regarding medical treatment near the end of life,[9] two areas of traditional State concern.

The question for the Attorney General under the CSA is whether Oregon practitioners are practicing in the "course of professional practice" (21 U.S.C. § 802(21)), or for a "medical purpose." *United States v. Moore*, *supra*, 423 U.S. at 137, n.13. This Court's review of generally accepted medical practices in *Moore* was limited to effectuating the "course of professional practice" standard, a screening device to detect drug diversion. Unlike in *Moore*, however, the Attorney General does not allege a single incident of drug diversion. And unlike in *Raich*, which involved the medical use of marijuana, the Attorney General does not allege a single use of a schedule I banned substance.

The Oregon Death With Dignity Act is a "prescribing law" only. Only Schedule II and lower drugs are prescribed. Oregon's novel law expressly prohibits "lethal injection, mercy killing [and] active euthanasia"[10] and requires that practitioners be licensed by the state Board of Medical

[9] See Or. Rev. Stat. 127.800 *et seq.* (Oregon Death With Dignity Act), appended, Practitioners' App. 1a-20a.

[10] Or. Rev. Stat. § 127.880 provides as follows:

> **Construction of Act.** Nothing in ORS 127.800 to 127.897 shall be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing or active euthanasia. Actions taken in accordance with ORS 127.800 to 127.897 shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law. [1995 c.3 §3.14]

Examiners and registered with the DEA. See Or. Rev. Stat. § 127.815(1)(L)(A), appended, Practitioners' App. 7a. The role of an attending physician is limited to caring for the patient and ensuring that all medical and legal criteria are satisfied before prescribing or dispensing controlled substances for use by the patient. Subsection 815(1)(k) provides, for example, that:

> (1) The attending physician shall: * * * (k) Ensure that all appropriate steps are carried out in accordance with ORS 127.800 to 127.897 prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner * * * .

Or. Rev. Stat. § 127.815(1)(k).

Dr. Rasmussen has demonstrated on this record that he and others like him practicing under the Oregon Death With Dignity Act are acting in their professional capacities in conformity with state law and the medical standard of care. In support of his request for permanent relief, Dr. Rasmussen averred that:

> 9. Prior to [the district] court's issuance of a temporary restraining order, my ability to meet the *community standard of care as established under Oregon law and practice* was severely restricted. As the direct result of th[e district] court's preliminary injunctive relief, my ability

> to meet the *community standard of care as established under Oregon law and practice* has been restored.

Practitioners' App. 24a, ¶ 9 (Rasmussen affidavit, emphasis added). Similarly, Dr. Rasmussen averred:

> 16. * * * . Due to Attorney General John Ashcroft's directive to enforce the Controlled Substances Act against physicians like myself practicing *in accord with Oregon law and the community standard of care*, and in the absence of a permanent injunction, I will no longer be able to meet the *community standard of care as established under Oregon law and practice*. I cannot risk DEA registration revocation proceedings or other sanctions, criminal and financial. I cannot risk my ability to practice as a medical oncologist, which has provided my livelihood for 21 years. Nor can I risk my family's security, or my ability to provide for my family.

See Practitioners' App. 26a, ¶ 16 (Rasmussen affidavit, emphasis added).

Only controlled substances are suitable for use under the Oregon Death With Dignity Act:

> 17. In the absence of a permanent injunction, the Oregon

Death With Dignity Act will be rendered useless. *Only controlled substances are suitable for use under the Oregon Death With Dignity Act*; they are used for what Oregon has determined to be *a legitimate medical purpose in the normal course of medical practice in Oregon*. These controlled substances are prescribed by physicians and dispensed by pharmacies for other purposes as well. Prescriptions for controlled substances under the Oregon Death With Dignity Act are written by state-licensed physicians and filled by state-licensed pharmacists, in full compliance with the closed system of procedures established by the CSA and enforced by the DEA. *These drugs are not otherwise available.*

See Practitioners' App. 26a-27a, ¶ 17 (Rasmussen affidavit, emphasis added).

As expressly required under the Oregon Death With Dignity Act, see Or. Rev. Stat. § 127.815(1)(L)(A), Dr. Rasmussen is registered with the state Board of Medical Examiners *and* the DEA. See Practitioners' App. 22a ¶¶ 1-2 (Rasmussen affidavit).

The standard of care for the attending physician practicing under the Oregon Death With Dignity Act is set out at Or. Rev. Stat. § 127.815 (attending physician responsibilities), appended, Practitioners' App. 5a-7a.

Consistent with those numerous statutory requirements, Dr. Rasmussen makes an initial determination of whether his patient has a terminal disease, is capable, and has made the request voluntarily. Dr. Rasmussen ensures that his patient is making an informed decision by informing the patient of the patient's medical diagnosis, prognosis, the potential risk and probable result associated with taking the medication to be prescribed, and the feasible alternatives, including, but not limited to, comfort care, hospice care and pain control. Dr. Rasmussen further refers his patients to a consulting physician for medical confirmation of his diagnosis and for a second opinion that the patient is capable and acting voluntarily. When appropriate, Dr. Rasmussen also refers his patients for counseling. He recommends that the patient notify next of kin and counsels the patient about the importance of having another person present when the patient takes the medication prescribed under Oregon law. See Practitioners' App. 24a-25a, ¶¶ 10-11 (Rasmussen affidavit).

As further required by Oregon's statutory standard of care, Dr. Rasmussen dispenses the medications directly, including ancillary medications intended to facilitate the desired effect and minimize the patient's discomfort or, in the alternative, Dr. Rasmussen contacts a pharmacist and informs the pharmacist of the prescription, and he then delivers the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician, or the patient's chosen agent. See Practitioners' App. 25a ¶ 12 (Rasmussen affidavit).

Dr. Rasmussen further satisfies all of the statutory medical documentation requirements and provides a copy of his dispensing record to the Department of Human Services. In sum, Dr. Rasmussen ensures that all appropriate steps are

carried out in accordance with Or. Rev. Stat. § 127.800 to 127.897 (see Practitioners' App. 25a, ¶ 13), as is required of him under state statutory and regulatory law, and the community standard of care. See, *e.g.*, Or. Rev. Stat. § 127.815. Dr. Rasmussen is at all times practicing medicine, acting for a medical purpose:

> 13. * * * . I comply with all the provisions of the Oregon Death With Dignity Act. I never engage in drug trafficking or diversion. As a physician practicing under the Oregon Death With Dignity Act, I am practicing *legitimate medicine in the course of my professional practice.*

See Practitioners' App. 25a, ¶ 13 (Rasmussen affidavit, emphasis added).

B. Criminal proceedings under the Controlled Substances Act; drug trafficking, drug diversion, and the "course of professional practice."

The CSA establishes both criminal and administrative recourse against those who violate its provisions. In a criminal prosecution to convict a DEA registered practitioner of unlawful distribution, the government must prove beyond a reasonable doubt that the practitioner:

(1) knowingly or intentionally;
(2) prescribed or dispensed a controlled substance;
(3) outside the course of professional practice.

These three elements of the crime are derived from the circular structure of the CSA.[11] The crime of unlawful distribution is a specific intent crime--the practitioner must have specifically intended ("knowingly or intentionally") to commit a criminal act.[12] This *mens rea* requirement applies to the second element (distribution) and to the third element (outside the course of professional practice).[13] It is not

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[11] It is a crime to (1) knowingly or intentionally (2) distribute or dispense a controlled substance unless "authorized" by the Act. See 21 U.S.C. § 841(a). Authorization is obtained by "registering" with the Attorney General. See 21 U.S.C. § 822(a)(2). Persons registered with the Attorney General are authorized to possess, manufacture, distribute, or dispense controlled substances to the extent authorized by their registration. See 21 U.S.C. § 822 (b). Physicians and pharmacists licensed by a state and registered with the Attorney General are "practitioners," and, as such, they are authorized to dispense controlled substances (see 21 U.S.C. § 829(a)&(b)) in "the course of [their] professional practice." See 21 U.S.C. § 802(21); see also *United States v. Moore*, 423 U.S. 122, 140 (1975).

[12] See, *e.g.*, 21 U.S.C. § 841(a); see also *United States v. Brower*, 336 F.3d 274, 276 (4th Cir. 2003) ("The Government's mens rea burden is defined under § 841(a), which makes it an offense to 'knowingly or intentionally' distribute a controlled substance"); *United States v. King*, 345 F.3d 149, 153 (2nd Cir. 2003) (" * * * § 841(a) contains a *mens rea* requirement: The trier of fact must determine that the defendant 'knowingly or intentionally' manufactured, distributed, dispensed, or possessed with intent to distribute a schedule I or II controlled substance").

[13] In *Arthur Andersen, LLP v. United States*, 125 S.Ct. 2129, 2135 (2005), this Court recently explained:

> We have recognized with regard to similar statutory language that the *mens rea* at least applies to the acts

(continued...)

enough to prove beyond a reasonable doubt that a practitioner knowingly or intentionally distributed a controlled substance, for *all* practitioners who prescribe or dispense controlled substances intend that much. Rather, it must be proven beyond a reasonable doubt that the practitioner intentionally departed *the course of professional practice--i.e.,* that the physician was no longer practicing medicine--but instead dealing drugs.[14]

In sharp contrast, the phrase "legitimate medical purpose" is not the value-laden phrase the Attorney General portrays it to be,[15] and the Attorney General misconstrues this Court's decision in *United States v. Moore*, when he argues as follows:

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[13](...continued)
that immediately follow, if not to other elements down the statutory chain.

[14] In *Arthur Andersen, supra*, this Court stressed the importance of, "limiting criminality * * * to reach only those with the level of 'culpability * * * we usually require in order to impose criminal liability.'" 125 S.Ct. at 2136; quoting *United States v. Aguilar*, 515 U.S. 593, 602 (1995).

[15] See, *e.g.*, Pet. Br. 10-11 (that "physician-assisted suicide is not a legitimate medical purpose is well supported by an 'overwhelming historical, legal, and medical consensus'"); 23 ("In light of the historical unanimity of opinion on this issue, and the fact that the CSA predated Oregon's DWDA by several decades, it is inconceivable that Congress, in enacting the CSA, regarded assisted suicide as a legitimate 'medical' practice in the 'treatment' of disease"); 23 ("Numerous health care experts have likewise agreed that physician-assisted suicide is not a legitimate medical treatment"); 24 ("In other federal laws and programs as well, physician-assisted suicide is not regarded as a legitimate medical practice").

> As this Court noted in *Moore*, the requirement that a controlled substance be prescribed for a *legitimate medical purpose* may be implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is, in any event, made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See *Moore*, 423 U.S. at 137-139 & n.13.

Pet. Br. 5 (emphasis added). Correctly stated, however, this Court in *Moore* said:

> The *medical purpose requirement* explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation § 306.04 makes it explicit.

Moore, 423 U.S. at 137, n.13 (emphasis added). The Attorney General has thus transformed "medical purpose," a phrase not inconsistent with the statutory phrase "course of professional practice," into the value laden term that he prefers, "legitimate medical purpose." This Court in *Moore* never went so far, and a simple word search indicates that the phrase "legitimate medical purpose" was used only one time, in footnote 12, when this Court quoted the text of 21 CFR § 1306.04(a) (formerly, § 306.04). See *Moore*, 423 U.S. at 136-137, n.12.

The Attorney General repeatedly removes *Moore* from its proper context. In *Moore*, this Court held that a physician who acts as a "'pusher'--not as a physician," violates the

CSA. *Id.* at 143.[16] *Moore* involved a physician who was convicted for drug diversion in violation of 21 U.S.C. § 841. The court of appeals overturned the conviction, holding that, "a physician registered under the Act is *per se* exempted from prosecution under § 841 because of his status as a registrant." *Id.* at 131. This Court reversed, holding that, "only the lawful acts of registrants are exempted." *Id.* The legislative history of the CSA, explained the Court, "indicates that Congress was concerned with the nature of the *drug transaction*, rather than with the status of the defendant." *Id.* at 134 (emphasis added). Citing the House Report, the Court concluded that a violation of the CSA, "was intended to turn on whether the '*transaction*' falls within or without *legitimate channels*." *Id.* at 135 (emphasis added). This Court explained that "[t]he evidence presented at trial was sufficient for the jury to find that [Dr. Moore's] conduct exceeded the bounds of 'professional practice.'" *Id.* at 142. That evidence, explained the Court, was sufficient to convince the jury that Dr. Moore "acted as a large-scale 'pusher'--not as a physician." *Id.* at 143. Thus, the Court equated acting

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[16] This Court summarized Dr. Moore's conduct as follows:

> [Dr. Moore] gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher"-not as a physician.

United States v. Moore, 423 U.S. 122, 142-143 (1975).

outside "the bounds of professional practice" with acting as a "pusher," diverting drugs outside of legitimate channels.

In *Moore*, this Court also described the "closed system" of regulation established by the CSA, *i.e.*, "Congress was particularly concerned with the diversion of drugs from *legitimate channels to illegitimate channels*." *Id.* at 135 (citing the House Report, emphasis added). Under the scheme fashioned by Congress, "[i]nstead of expressly removing from the protection of the Act those physicians who operate beyond the bounds of professional practice, the CSA uses the concept of 'registration.'" *Id.* at 140. The federal registration "contemplates that [the physician] is *authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice." *Id.* at 141 (emphasis added). The federal registration, explained the Court, "extends no further. It authorizes transactions within 'the *legitimate distribution chain*' and makes all others illegal." *Id.* (emphasis added). Implicit in a physician's registration, "is the understanding that he is authorized only to act 'as a physician.'" *Id.* This understanding reflects Congressional recognition that "registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for *diversion*, were responsible for a large part of the illegal drug traffic." *Id.* at 135 (emphasis added).

Thus the question, whether a physician is prescribing in the course of his or her professional practice, simply asks whether the controlled drugs remain within the "closed system," or within "legitimate channels" or with a "legitimate distribution chain." A review of the case law interpreting the phrase, "course of professional practice," including *Moore, supra*, further reveals that until recently DEA enforcement activity has focused exclusively upon drug abuse or diversion

flowing from egregious departures from the course of professional practice.

In *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973), the court equated "the course of professional practice" to "within the bounds of professional practice," or the opposite of the physician as drug pusher:

> Manifestly the language "in the course of professional practice" is intended to limit the immunity of a licensed practitioner. It is apparent that a licensed practitioner is not immune from the act solely due to his status * * * but rather because he is expected to prescribe or dispense drugs *within the bounds of his professional practice of medicine*. * * * . However, under the guise of treatment a physician cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict. * * * *Congress did not intend for doctors to become drug "pushers."*

Collier, 478 F.2d at 271-72 (emphasis added). In *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978), the court acknowledged the difficulty of direct application of the *Collier* interpretation in close-call cases, prompting the court to describe its dilemma this way:

> Our facile quotation of general principle does not diminish the difficulty in its application. A majority

> of cases have dealt with facts which were so blatant that a statement of clear cut criteria in a form useful in other cases would have been superfluous to the decision. We are, however, able to glean from reported cases certain recurring concomitance of condemned behavior, examples of which include the following [nine factors.]

Rosen, 582 F.2d at 1035-36. The *Rosen* court then listed nine behaviors from the case law that may be present when a physician is diverting drugs, *i.e.*, practicing medicine outside the "course of professional practice," as follows:

1. An inordinately large quantity of controlled substances was prescribed;
2. Large numbers of prescriptions were issued;
3. No physical examination was given;
4. The physician warned the patient to fill prescriptions at different drug stores;
5. The physician issued prescriptions to a patient known to be delivering the drugs to others;
6. The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment;
7. The physician involved used street slang rather than medical terminology for the drugs prescribed;
8. There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing; and

9. The physician wrote more than one prescription on occasions in order to spread them out.

Rosen, 582 F.2d at 1036.

Both *Collier* and *Rosen* demonstrate that even in cases involving "close call" medical judgment, the only relevant issue under the CSA is whether legitimate drugs are being diverted into illicit channels. When the courts compare the practitioner's conduct against professional practice standards, the only purpose is to screen for diversion of controlled substances; the "course of professional practice" standard, 21 U.S.C. § 802(21), is simply a screening device intended to preserve the closed system of regulation. See also *Humphreys v. DEA*, 96 F.3d 658, 666 (3rd Cir. 1996) (reversing DEA's decision to revoke a physician's registration because the evidence proffered by DEA showed that the potential for diversion "is so unlikely as to be unsustainable"); *United States v. Rosenberg*, 515 F.2d 190, 197, 199 (9th Cir. 1975) (affirming conviction based on the jury's finding, "that Dr. Rosenberg was not acting in the course of his professional practice" after the jury was instructed that the CSA was violated if Dr. Rosenberg, "was not acting in good faith as a doctor, but simply pushing pills"). Remarkably, in the instant case, the Attorney General fails to allege a single violation of the closed system of regulation, and instead invokes 21 C.F.R. § 1306.04 as authority to pass judgment on the "legitimacy" of medical policy in the States. The rule and the statute, however, mean the same thing, *Moore*, 423 U.S. at 137, n.13. In other words, a prescription is written for a "medical purpose" if it is written in the "course of professional practice." *Id.* If there is any disagreement between the rule and the statute, the rule must give way to the statute.

C. Administrative proceedings under the Controlled Substances Act; revocations, denials, and the "public interest."

A violation of the "course of professional practice" standard is also actionable in administrative proceedings.[17] Although, in an administrative proceeding, the burden of proof is lower and the sanctions less severe, the meaning of the phrase "course of professional practice" remains the same, rendering further analysis of this phrase unnecessary.

In an administrative context, however, the Attorney General goes one step further and concludes as a matter of law that medical practice under the Oregon Death With Dignity Act is not in the "public interest," thereby empowering the DEA to revoke existing registrations and deny new applications.

The impact upon medicine in the State of Oregon is undeniable. The Oregon Death With Dignity Act requires that practitioners possess a DEA registration and, as this record makes clear, schedule II drugs are not only used under the Oregon Death With Dignity Act, they are also necessary, and there are no substitutes. See discussion *supra*, 12, n.6 & 17-18. Consequently, the power to revoke or deny the DEA registrations of those who practice under the Oregon Death With Dignity Act is the power to regulate medicine in Oregon.

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[17] See, *e.g.*, *William J. Roth, M.D.*, 60 Fed. Reg. 62262 (1995); *William F. Skinner, M.D.*, 60 Fed. Reg. 62887 (1995); *Paul W. Saxton, D.O.*, 64 Fed. Reg. 25073 (1999); *Wesley G. Harline, M.D.*, 65 Fed. Reg. 5665 (2000).

The Attorney General's role in construing the "public interest" flows from a 1984 amendment to the CSA. It is not, however, the expansive grant of power that the Attorney General portrays it to be. Congress, once again concerned about the diversion of controlled substances from legitimate to illicit channels by physicians and pharmacists who had easy access via their DEA registrations, sought to give the Attorney General more leeway when issuing and revoking DEA registrations. Congress was motivated by the fact that the States were often slow to take action. The solution, aptly named, was the Dangerous Drug Diversion Control Act of 1984, the relevant section of which is now codified at 21 U.S.C. § 823(f)(1)-(5), under which section the Attorney General is empowered to deny, "an application for * * * registration if he determines that the issuance of such registration would be inconsistent with the *public interest*." 21 U.S.C. § 823(f) (emphasis added). The Attorney General's power to construe the public interest is narrowly circumscribed, however. Congress mandated that when "determining the public interest," the Attorney General "shall" consider the following five factors:

> (1) The recommendation of the appropriate *State licensing board or professional disciplinary authority*.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's *conviction record under* Federal or *State laws* relating to the manufacture, distribution, or dispensing of controlled substances.

> (4) *Compliance with applicable State*, Federal, *or local laws* relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f)(emphasis added).[18] As such, the Attorney General's discretion to determine the "public interest" has clear limits. Although the phrase "public interest" is itself broad and abstract, Congress dictated five criteria that "shall" be considered when determining the public interest under the CSA. *Id.* Three of those criteria direct the Attorney General to consult state law. 21 U.S.C. § 823(f)(1),(3)&(4). The remaining two subsections, although not expressly referencing state law, certainly include state law. 21 U.S.C. § 823(f)(2)&(5). Inasmuch as the 1984 amendment was partially in response to the perceived slow action of the States, the five factors set out in 21 U.S.C. § 823(f)(1)-(5) are best viewed as placing the Attorney General "in the shoes" of the State, to empower the Attorney General to make a determination similar to a State's determination, had the State acted first. In no event does § 823(f)(1)-(5)

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[18] A corresponding amendment was made to 21 U.S.C. § 824(a), which applies to the *revocations* of § 823 *registrations*, listing five "grounds" for revocation. The criteria for revocation differ from the criteria applicable when granting an initial registration, except that § 824(a)(4) incorporates by reference the § 823(f) "public interest" requirement. Consequently, the public interest is relevant to both initial registrations and subsequent revocations.

empower the Attorney General to ignore or reject state law, as he has in the instant case.[19]

The Attorney General's desire to reject state law is further remarkable in view of the fact that during the first 14 years of the CSA, the only thing that mattered was the practitioner's compliance with state law:

> *Practitioners shall be registered* to dispense * * * controlled substances in schedule II, III, IV, or V *if they are authorized to dispense or conduct research under the law of the State in which they practice.* * * * .
>
> *Pharmacies* (as distinguished from pharmacists) when engaged in commercial activities, *shall be registered* to dispense controlled substances in schedule II, III, IV, or V *if they are authorized to dispense under the law of the State in which they regularly conduct business.*

Former 21 U.S.C § 823(f) (emphasis and paragraphing added); see also, *Moore*, 423 U.S. at 140-141 ("Registration of physicians and other practitioners * * * is mandatory if the applicant is authorized to dispense drugs or conduct research under the law of the State in which he practices"). The *Moore* decision relied upon the House Report explanation that DEA registration is "a matter of right" where the practitioner is using the controlled substances in compliance with state law:

> The House Report described the rationale behind § 823(f) as follows: "Practitioners * * * engaged in the distribution chain would be required to be registered, but *registration would be as a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law* * * * ."

Id. at 141, n.19 (emphasis added). Prior to the 1984 amendment, then, the Attorney General's role was clerical, limited to issuing DEA registrations so long as the applicant was authorized under state law. Consequently, it is an amazing contention by the Attorney General today that, as a result of a 1984 amendment, he is newly empowered to reject state law and exert *de facto* control over the practice of medicine in the States when, prior to 1984, he had no choice but to follow state law.

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[19] Limiting the "public interest" clause, as well as the catchall provision found in subsection (f)(5) ("such other conduct") to the consideration of federal, state and local law is consistent with the maxim, *ejusdem generis*:

> the statutory canon that "where general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words."

Circuit City Stores, Inc. v. Adams, 532 U.S 105, 114-115 (2001); quoting, 2A N. Singer, *Sutherland on Statutes and Statutory Construction* § 47.17 (1991).

D. The Congressional record establishes that the Controlled Substances Act is an anti-drug law-enforcement statute, not a medical practices act

The legislative record demonstrates that the CSA is a law-enforcement statute and that Congress never intended that it would be used to regulate medicine or to alter the state/federal framework. The following excerpts from the 1970 Senate floor debate reveal that the CSA was at first focused solely upon preventing drug trafficking and diversion; it served a law-enforcement purpose and no other purpose:

> This measure--in concept, in spirit, and in detail--*is a law-enforcement measure.* It only approaches one side of the problem of drug abuse.

Quoting Senator Hughes, 116 Cong. Rec. 973 (1970) (emphasis added).

> That is my position on this problem. The legislation before us is a *law enforcement bill.* * * * we concluded it would be better to keep this particular piece of legislation *a law enforcement measure.*

Quoting Senator Dodd, 116 Cong. Rec. 976 (1970) (emphasis added).

> The proposed legislation provides a regulatory schedule for the lawful manufacture, distribution, and

> dispensing of controlled drugs to furnish us with better law enforcement tools *so that the rampant drug abuse problem can finally be curbed* effectively.

Quoting Senator Dodd, 116 Cong. Rec. 978 (1970) (emphasis added).

> But it cannot be overemphasized that the bill before the Senate today is *entirely concerned with enforcement.* It contains no medical or rehabilitative provisions.
>
> It is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls. * * * .

Quoting Senator Dodd, 116 Cong. Rec. 978 (1970) (emphasis added).

> * * * this title reaffirms the Federal Government's role in drug control. Basically this role is to regulate the legitimate drug trade *to prevent diversion of medically useful dangerous drugs into illegitimate channels and to help reduce the criminal traffic* in all narcotic and dangerous drugs on the local, national, and international level.

Quoting Senator Dodd, 116 Cong. Rec. 996 (1970) (emphasis added).

> *All of these provisions are designed to reduce the diversion of drugs* from the legitimate course of commerce and use *into illegal channels*. This is important in the face of evidence that about half of the annual production of amphetamine and barbiturate drugs, or between 8 and 9 billion pills, *have been diverted to nonmedical use*.

Quoting Senator Dodd, 116 Cong. Rec. 996 (1970) (emphasis added).

The debate changed little as it moved to the House. The primary difference was that the House expanded the legislation to include drug research, education and treatment, in addition to the Senate's narrower focus upon the prevention of drug trafficking and diversion. The entire debate remained, however, in the context of the drug problem:

> There are a limited number of approaches to attack this problem—preventive steps, aimed at stopping experimentation before it starts; control, to regulate the supply and availability of drugs; rehabilitation to lead individuals away from drug dependence and addiction. It is my conviction that the Federal Government must make a concentrated effort in all of these areas.

Quoting Representative Boland, 116 Cong. Rec. 33,315 (1970).

> The word "control" in the title, of course, simply means enforcement by the Justice Department in *problems related to drug abuse*, by any person or corporation whether a manufacturer, wholesaler, or retailer. These controls cover all the hard narcotics and opiates, marihuana, and hallucinogens such as LSD, amphetamines, barbiturates, and even any tranquilizers subject to abuse.

Quoting Representative Randall, 116 Cong. Rec. 33,656 (1970) (emphasis added).

Here again, nothing from the 1970 House floor debate remotely suggests that Congress intended the Attorney General to determine the "legitimacy" of medicine, or to establish medical policy in the States. To better control the rampant drug problem, the House expanded the reach of the CSA to include drug research, education, treatment, and rehabilitation, but included not a word about regulating medical practice. The relevant language in the proposed legislation did not significantly change when it returned to the Senate later that same year:

> I am particularly grateful that the basic Controlled Dangerous Substances Act was passed in almost its entirety by the House. There were a number of minor disagreements; but more than 90 percent of the law which was reported by the Senate

> Subcomittee [sic] on Juvenile Delinquency will soon become the law of the land.
>
> .
>
> This is no mean achievement. The Senate legislation passed the very close scrutiny of the House[,] which investigated the bill for many months. No significant changes were made, a procedure which does not often occur in bills sent over from the Senate.

Quoting Senator Dodd, 116 Cong. Rec. 35,051-52 (1970).

Fourteen years later, the 1984 amendments reveal that once again Congress was concerned about a rampant drug abuse problem, the diversion of otherwise lawful drugs to illicit or recreational uses. The bill was aptly named the Dangerous Drug Diversion Control Act of 1984 and it was described as follows:

> Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5656) to amend the Controlled Substances Act *to strengthen the authority to prevent diversion of controlled substances*, and for other purposes, as amended.

Quoting Representative Hughes, 130 Cong. Rec. 25,846 (1984) (emphasis added).

> This bill addresses one of the most critical areas of drug abuse, the abuse of prescription drugs. Prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse. But I am sorry to say this aspect of drug abuse, *the diversion problem*, has often failed to get the societal or the enforcement attention that it deserves.

Quoting Representative Hughes, 130 Cong. Rec. 25,848 (1984) (emphasis added). The Attorney General would likely take the "deaths and injuries" phrase above out of context, just as he does in his petition and brief (see Pet. Cert. 23; Pet. Br. 45: "misuse of a drug in suicides and attempted suicides"), but the Congress was only concerned with *illicit use* flowing from "diversion":

> *Diversion* is the connotation for the various means by which legitimate medical controlled substances are diverted from proper use to improper use. Invalid prescriptions and pharmacy robberies are two types of retail level *diversion*. While much of the drug enforcement focus has been placed on the interdiction of improperly imported substances, *the problem of domestic diversion has quietly grown to staggering proportions*.
>
> * * * . Abuse of prescription drugs through *diversion* at the manufacturing and distribution levels [is] severely

> curtailed under current law by DEA. The vast majority of *diversions* occur at the retail level. * * * .
>
> * * * * *
>
> * * * . *This bill provides the Drug Enforcement Agency with the necessary tools to join State agencies in reducing diversion.*

Quoting Representative Sawyer, 130 Cong. Rec. 25,849 (1984) (emphasis added).

> Mr. Speaker, I rise in strong support of H.R. 5656, the *Dangerous Drug Diversion Control Act* of 1984. The bill amends the Controlled Substances Act to attempt *to prevent the diversion of controlled substances from legitimate channels of medical distribution and administration to illegitimate channels for purposes of abuse.* Evidence suggests that prescription drugs *diverted* by legitimate medical distributors to the illicit drug market accounts for about three-fourths of deaths and injuries due to drug abuse.

Quoting Representative Gilman, 130 Cong. Rec. 25,851 (1984) (emphasis added).

In sum, whether reviewing the 1970 or the 1984 legislative history, it is clear that the CSA was intended as a solution to the problems of illicit drug use, drug trafficking,

and drug diversion. Congress never intended through the CSA to empower the Attorney General to rule upon the legitimacy of medical practice in the States.

II. The States, not the Attorney General acting through the Controlled Substances Act, regulate medicine.

The Attorney General's current interpretation of "legitimate medical purpose" and the "public interest" results in the direct regulation of medicine in the States and indeed the Attorney General argues for a national standard of care, *e.g.*, that "the 'standard of medical practice generally recognized and accepted' for purposes of the CSA, * * * is a national one." Pet. Br. 35, quoting *Moore*, *supra*, 423 U.S. 122, 139.

The Attorney General further argues that there is a trend away from the "locality rule" applicable in medical malpractice actions, Pet. Br. 36, and complains that if the CSA "incorporates the views of each of the 50 States * * *, [then] the *prosecution of physicians* would become much more difficult." Pet. Br. 35 (emphasis added).

The Attorney General commits several errors. First, with respect to prosecuting physicians, fifty different state malpractice standards should be of no consequence to the Attorney General because malpractice--or ordinary medical negligence--even when it involves controlled substances, is not a criminal act. See nn. 11-14, *supra*.

Second, the "locality rule" presents an *intra*state issue only. In those states that have dispensed with the locality rule, they have merely decided that the standard of care shall

be uniform throughout the state, in both rural and urban settings, meaning that the rural practitioner is no longer held to a lesser standard of care than is his or her big-city counterpart. Thus, to the extent that a state dispenses with the locality rule, it is a state-level decision only, it impacts civil malpractice actions only, and it has no impact on federal drug diversion prosecutions where the issue is whether a DEA-registered practitioner is diverting controlled substances out of the closed system, from legitimate to illicit channels.

Third, although some highly urban states have adopted a standard of care that speaks in "national" terms,[20] these

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[20] Rhode Island provides a good example of the rationale behind the adoption of a national standard of care:

> In sum, the traditional locality rules no longer fit the present-day medical malpractice case. * * *
>
> * * * the Legislature failed to employ any reference to the "similar locality" rule. We conclude that this omission was deliberate and constitutes a recognition of the national approach to the delivery of medical services, *especially in the urban centers of this country, of which Rhode Island is certainly one.*
>
> Accordingly we join the growing number of jurisdictions that have repudiated the "same or similar" communities test in favor of a national standard and hold that a physician is under a duty to use the degree of care and skill that is expected of a reasonably competent practitioner in the same class to which he or she belongs, acting in the same or similar circumstances.

Sheeley v. Memorial Hosp., 710 A.2d 161, 166-167 (R.I., 1998) (emphasis added).

states are in the minority.[21] More importantly, a state's decision to adopt a so-called national standard of care remains a state-level decision, requiring the exercise of state power; it does not mean that a state has surrendered its traditional role to regulate medicine, or to legislate exceptions to its "national" standard of care.

Fourth, and perhaps most importantly, Oregon has decided. When Oregon enacted, amended, and implemented its Death With Dignity Act, it established the standard of care regarding medical treatment near the end of life. Oregon also continues its tradition of a community standard of care, complete with a locality rule:

> **Duty of care;** * * * (1) A physician * * * licensed to practice medicine * * * by the Board of Medical Examiners for the State of Oregon has the duty to use that degree of care, skill and diligence that is used by ordinarily careful physicians * * * in the *same or similar circumstances in*

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[21] Contrary to the Attorney General's argument that a national standard of care predominates (Pet. Br. 36), more modern authority than that cited by the Attorney General reveals that more than 30 years later, less than half the states joined the trend that started in the 1970s. See, *e.g. Estate of Hagedorn ex rel. Hagedorn v. Peterson*, 690 N.W.2d 84, 89 (Iowa, 2004) (modified locality rule); *Jinkins v. Lee,* 807 N.E.2d 411, 421 (Ill., 2004) (locality rule); *LaFramboise v. Thompson* 329 F.Supp.2d 1054, 1056 (D.N.D., 2004) (locality rule); *see, also,* James O. Pearson, Jr., J.D., *Modern Status of "Locality Rule" in Malpractice Action Against Physician Who is Not a Specialist*, 99 A.L.R.3d 1133 (1980) (updated through 2004).

> *the community of the physician* * * *
> or a *similar community*.

Or. Rev. Stat. § 677.095 (emphasis added).

The Attorney General is no more empowered to reject the standard of care set out in the Oregon Death With Dignity Act than he is to reject Oregon's community standard of care, or its locality rule. These are state-level decisions, and it is the States, not the Federal Government, that regulate medicine. See, *e.g.*, *Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government"); *Liggett Co. v. Baldridge*, 278 U.S. 105, 112 (1928) (the States have authority to regulate drug prescriptions and pharmacists); *Semler v. Dental Examiners*, 294 U.S. 608, 611 (1934) (Oregon has authority to regulate the practice of dentistry within its borders); *United States v. Oregon Med. Soc.*, 343 U.S. 326, 338 (1951) (practice of medicine within Oregon is not interstate commerce); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1953) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power"); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (determination of medical necessity and standards of reasonable care are "quintessentially state-law" determinations). Although the Attorney General criticizes *Linder*, *supra*, as an outdated *Lochner*-era opinion (Pet. Br. 37, 40), similar propositions are found in *Barsky* and *Rush Prudential HMO*, *supra*.

This is no small point of dispute. The framers of the Constitution "split the atom of sovereignty" two ways:

horizontally among the three branches of government and vertically between the federal and state governments. See *Alden v. Maine*, 527 U.S. 706, 714-15, 751 (1999); *Printz v. United States*, 521 U.S. 898, 921-22 (1997). As this Court recently explained:

> This separation of the two spheres is one of the Constitution's structural protections of liberty. "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, *a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.*"

Printz, 521 U.S. at 921 (emphasis added); quoting *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

The Congress, when legislating and later amending the CSA, was certainly aware of the traditional and constitutional allocation of power that resides at the core of our federal form of government, and it expressly provided that, "absent a positive conflict," the CSA does not prohibit the states from legislating on, "subject matter which would otherwise be within the authority of the State." See 21 U.S.C. § 903.[22]

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[22] Section 903 (Application of State law) provides:

(continued...)

Thus, the Attorney General may enforce the "uniform national policy" intended by Congress to prevent illicit drug use, drug trafficking, and drug diversion and, at the same time, Oregon practitioners acting in accord with state law, authorized by the Board of Medical Examiners and registered with the DEA, may possess, prescribe, and/or dispense schedule II substances within "the course of their professional practice," and in the "public interest." These two policies are not mutually exclusive, and there is no positive conflict between state and federal law such that the two "cannot consistently stand together." 21 U.S.C. § 903. In view of the plain language of the CSA, decades of jurisprudence, and the demonstrated intent of Congress, all discussed above, the Attorney General's contrary interpretation of the CSA and its implementing regulations seeks to accomplish too much. See *Raygor v. Regents of University of Minnesota,* 534 U.S. 533, 543 (2002) ("When Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute")(internal quotation marks omitted).

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[22](...continued)

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress *to occupy the field in which that provision operates*, including criminal penalties, to the exclusion of any State law on the same subject matter *which would otherwise be within the authority of the State*, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903 (emphasis added).

III. The power to regulate commerce between the States does not authorize federal usurpation of medical practice in the States, or the manner in which Oregonians die.

For the purposes of this discussion, the power of Congress to schedule or ban drugs, or to create a closed system or regulation, is not challenged. However, the Attorney General's expansive reinterpretation of 21 C.F.R. § 1306.04 (legitimate medical purpose) and 21 U.S.C. § 823(f) (public interest), does nothing to further those ends.

Congress, unlike the States, does not possess a general police power. *United States v. Lopez*, 514 U.S. 549, 566-67 (1995). Rather, "[e]very law enacted by Congress must be based on one or more of its powers enumerated in the Constitution." *United States v. Morrison*, 529 U.S. 598, 607 (2000). The commerce power is the power, "to prescribe the rule by which commerce is to be governed." *Lopez*, 514 U.S. at 553; quoting, *Gibbon v. Ogden,* 9 Wheat. 1, 196 (1824). Congress may not, "use a relatively trivial impact on commerce as an excuse for broad general regulation of state or private activities." *Lopez,* 514 U.S. at 558. Although statutes come to the courts bearing a presumption of constitutionality, *Morrison*, 529 U.S. at 607, any enactment that purports to be premised upon the commerce clause must in fact bear a substantial relationship to the regulation of interstate commerce. See, *e.g.*, *id.* at 613-19 (Congress lacked authority to establish tort remedy for violence based on gender); *Lopez,* 514 U.S. at 561-67 (Congress lacked authority to prohibit carrying a gun within 1000 feet of a school; impact upon interstate commerce was too attenuated).

Congressional enactments premised upon the power to regulate commerce are more carefully scrutinized when they invade areas of "traditional state concern." See, *e.g.*, *Lopez*, 514 U.S. at 564-68. Regulating the practice of medicine has long been regarded as a traditional state concern. See discussion and authorities, *supra*, 41-45. To uphold the Attorney General's enforcement directive is to go from regulating drug trafficking and diversion into regulating the practice of medicine within the states, a line that may not be crossed:

> The authority of the federal government may not be pushed to such an extreme as to destroy the distinction, which the commerce clause itself establishes, between commerce "among the several States" and the internal concerns of a State. That distinction * * * is vital to the maintenance of our federal system.

Labor Board v. Jones & Laughlin, 301 U.S. 1, 30 (1937).

Each Congressional enactment and subsequent interpretation must stand or fall on its own merits. The provision at issue in *Lopez* was section 1,702 of the Crime Control Act of 1990. This Court did not ask whether sections 1 through 1,701 were valid, or pertained to interstate commerce, but focused exclusively upon section 1,702. Here, the similarly narrow question is whether the Attorney General's expansive reinterpretation of a 1984 amendment (see 21 U.S.C. § 823(f)--"public interest") and an agency rule (see 21 C.F.R. § 1306.04--"legitimate medical purpose"), exceeds the Commerce Clause power.

The prescriptions in question are issued by state-licensed physicians, and filled by state-licensed pharmacists, in full compliance with the closed system of control established by the CSA. The prescriptions are to be used for what the State of Oregon has determined is within the course of professional practice. The medications are types commonly prescribed by physicians, and there are no allegations that these prescriptions have or will enter into the stream of illicit commerce. The Federal Government's legitimate interest in regulating interstate commerce has been fulfilled.

The concerns that led to this Court's decision in *Raich* do not apply here. Prescribing controlled substances to dying Oregonians for use as authorized by the State would not "leave a gaping hole" in the closed system of regulation, and prohibiting such use is not "necessary and proper" to prevent drug trafficking or drug diversion, which is the core purpose of the CSA, especially those provisions upon which the Attorney General relies. Indeed, the Attorney General does not, and cannot, point to a hole in the closed system that his new interpretation fills, nor can he explain how the purpose of the CSA would be undercut if this activity is not regulated.

Although the Constitution grants certain powers to Congress, the States have a constitutionally-protected role in the federal scheme as, "residuary sovereigns and joint participants in the governance of the Nation." *Alden*, *supra*, 527 U.S. at 748. The rights of the States are not confined to those expressly enumerated in the text of the Constitution, but also include other rights recognized at the time the Constitution was ratified or implicit in its design. Id. at 713-15, 728-32. "[I]t was neither necessary nor proper to define the powers retained by the States" because they retain all

powers they had before enactment of the Constitution, "except so far as they may be abridged by that instrument." *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 801 (1995); quoting *Sturges v. Crowninshield*, 4 Wheat. 122, 193 (1819).

Just as judicial enforcement of "separation of powers" prevents one branch from usurping functions reserved for another branch, the courts similarly enforce the vertical separation of powers, to keep the Federal Government from usurping the powers and role reserved for the States. *Morrison*, 529 U.S. at 616-17, n.7. Here, the Attorney General's enforcement directive, specifically his expansive reinterpretation of 21 C.F.R. § 1306.04 (legitimate medical purpose) and 21 U.S.C. § 823(f) (public interest), is a direct attempt to regulate medical practice in the States, and it therefore exceeds not only the scope of the CSA, but also the limits of the Congressional power to regulate commerce.

CONCLUSION

FOR THE FOREGOING REASONS, this Court is urged to affirm the Ninth Circuit Court of Appeals.

Respectfully submitted,

ELI D. STUTSMAN
Counsel of Record
621 SW Morrison
Thirteenth Floor
Portland, OR 97205
(503) 274-4048

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29

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IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ of Certiorari
To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR THE PATIENT-RESPONDENTS

NICHOLAS W. van AELSTYN
Counsel of Record
AARON S. JACOBS
DAVID A. THOMAS
HELLER EHRMAN LLP
333 Bush Street
San Francisco, California 94104-2878
Telephone: 415-772-6000
Facsimile: 415-772-6268

Counsel for
PATIENT-RESPONDENTS

KATHRYN L. TUCKER
COMPASSION & CHOICES
1201 3rd Avenue, 40th Floor
Seattle, Washington 98101-3000
Telephone: 206-367-2134
Facsimile: 206-583-8500

Counsel for
PATIENT-RESPONDENTS

QUESTION PRESENTED

Exercising its traditional police powers, Oregon enacted a law that empowers mentally competent, terminally ill Oregonians to request and receive a prescription from their physician for medications to choose the time, place, and manner of their impending deaths. In enacting and amending the Controlled Substances Act (CSA), did Congress clearly authorize the Attorney General to determine that physicians and pharmacists acting in accordance with Oregon law have violated the CSA?

PARTIES TO THE PROCEEDING

Petitioners are Alberto R. Gonzales, Attorney General of the United States; Karen Tandy, Administrator of the Drug Enforcement Administration; Kenneth W. McGee, Assistant Special Agent-in-Charge of the Portland Office of the Drug Enforcement Administration; the United States of America; the United States Department of Justice; and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, John Doe #1 and Don W. James.

TABLE OF CONTENTS

	Page
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	1
STATUTES AND REGULATIONS INVOLVED	2
STATEMENT OF THE CASE	2
ARGUMENT	9
I. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference	9
A. Ashcroft's Interpretation of the CSA Is Not Entitled to Heightened Deference Under *Chevron*.	10
1. The *Mead* and *Barnhart* factors preclude *Chevron* deference.	11
2. Ashcroft's interpretation is entitled to little respect under *Skidmore*	20
B. Ashcroft's Interpretation of Section 1306.04 Is Not Entitled to *Seminole Rock* Deference.	22
1. The Ashcroft Directive brings Section 1306.04 too close to the constitutional line.	23
2. The Ashcroft Directive pushes Section 1306.04 beyond the boundaries of the CSA.	24

Page

3. Section 1306.04 was not intended to federalize the practice of medicine.... 25

4. The Ashcroft Directive is inconsistent with the Department of Justice's prior interpretation..... 27

II. Petitioners' Contention that the Directive Sets Forth the "Prevailing View" of Physician-Assisted Dying is Unsupported and Unsupportable..... 28

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying. 30

B. The Data Regarding Oregon's Experience with the Dignity Act Demonstrate that Legal, Physician-Assisted Dying Poses No Threat to the Public Health and Safety. 35

C. Physician-Assisted Dying Comports with the Five Statutory Factors Required by § 823(f). 41

III. In Grappling with the Issue of Assisted Dying, Oregon Is Fulfilling its Intended Role as a State Laboratory of Social Experimentation.... 44

CONCLUSION..... 50

TABLE OF AUTHORITIES

Page

Cases

Alaska Dept. of Environmental Conservation v. EPA, 540 U.S. 461 (2004)..... 12

Arizona v. Evans, 514 U.S. 1 (1995)..... 45

Atkins v. Virginia, 536 U.S. 304 (2002)..... 46

Barnhart v. Walton, 535 U.S. 212 (2002)..... 11, 13

Barsky v. Bd. of Regents, 347 U.S. 442 (1954).... 24

Bowen v. Georgetown Univ. Hospital, 488 U.S. 204 (1988)..... 23

Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945) 22, 24, 28

Boy Scouts of America v. Dale, 530 U.S. 640 (2000)..... 46

Bristol Myers Squibb v. Shalala, 91 F.3d 1493 (D.C. Cir. 1996) 24

Caruso v. Blockbuster-Sony Music Entertainment Centre, 193 F.3d 730 (3d Cir. 1999) 25

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) 10, 12, 23

Christensen v. Harris County, 529 U.S. 576 (2000)..... 11, 20

Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261 (1990) 16, 24, 47

	Page
Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council, 485 U.S. 568 (1988)	23
EEOC v. Wyoming, 460 U.S. 226 (1983)	45
Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528 (1985)	45
General Dynamics Land Systems, Inc. v. Cline, 540 U.S. 581 (2004)	9
Globe Newspaper Co. v. Superior Court for Norfolk County, 457 U.S. 596 (1982)	47
Glucksberg v. Washington, 850 F. Supp. 1454 (W.D. Wa. 1994)	5
Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975)	24
Gonzales v. Raich, 545 U.S. __, 125 S. Ct. 2195 (2005)	2, 3, 15, 21, 46
Hall v. EPA, 273 F.3d 1146 (9th Cir. 2001)	22, 28
James v. Von Zemenszky, 301 F.3d 1364 (Fed. Cir. 2002)	11
La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355 (1986)	23
Lee v. Oregon, 107 F.3d 1382 (9th Cir. 1997)	5
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)	24, 49
Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Auto Insurance, 463 U.S. 29 (1983)	18, 19

	Page
NationsBank of N.C., N.A. v. Variable Annuity Life Insurance Co., 513 U.S. 251 (1995)	12
New State Ice Co. v. Liebmann, 285 U.S. 262 (1932)	45
NLRB v. Brown, 380 U.S. 278 (1965)	22
Norfolk Southern Railway, Co. v. Shanklin, 529 U.S. 344 (2000)	22, 27, 28
Oregon v. Ashcroft, 192 F. Supp. 2d 1077 (D. Or. 2002)	1, 8, 21
Oregon v. Ashcroft, 368 F.3d 1118 (9th Cir. 2004)	*passim*
Quill v. Koppel, 870 F. Supp. 78 (S.D.N.Y. 1994)	5
San Antonio Independent School Dist. v. Rodriguez, 411 U.S. 1 (1973)	46
Santosky v. Kramer, 455 U.S. 745 (1982)	45
Skidmore v. Swift & Co., 323 U.S. 134 (1944)	10, 20
Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers, 531 U.S. 159 (2001)	23, 28
Thomas Jefferson Univ. v. Shalala, 512 U.S. 504 (1994)	25, 27
Trawick v. DEA, 861 F.2d 72 (4th Cir. 1988)	4

Page

United States v. Lopez,
514 U.S. 549 (1995) 45

United States v. Mead Corp.,
533 U.S. 218 (2001) 10, 11, 12

United States v. Moore,
423 U.S. 122 (1975) 3, 25

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001) 21, 46

Vacco v. Quill, 521 U.S. 793 (1997) 6

Washington v. Glucksberg,
521 U.S. 702 (1997) 6, 38, 44, 47

Zelman v. Simmons-Harris, 536 U.S. 639 (2002) ... 46

Statutes, Regulations and Legislative Materials

21 U.S.C. § 801 ..... 3, 24

21 U.S.C. § 801a(1) 3

21 U.S.C. § 811(b) 15

21 U.S.C. § 812 21

21 U.S.C. § 823 42

21 U.S.C. § 824(a)(4) 42

66 Fed. Reg. 56,607 (November 9, 2001) 8

116 Cong. Rec. 977 (1970) 3, 4

130 Cong. Rec. 1,586 (1984) 4, 5

Or. Rev. Stat. § 127.865 35

Page

Pub. L. No. 91-513, 84 Stat. 1236 24

Pub. L. No. 91-513, 84 Stat. 1253, 1255 27

A.B. 654, 2005 Sess. (Cal. 2005), *available at* http://www.aroundthecapitol.com/billtrack/billview.html?bill=AB_654 48

Comments and Objections to Part 306,
36 Fed. Reg. 7777 (1971) 26

H.R. 168, 2005 Leg., 2005-06 Sess. (Vt. 2005); text *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/bills/intro/H-168.HTM 48

H.R. 318, 2003 Leg., 2003-04 Sess. (Vt. 2004), *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2004/bills/intro/H-318.HTM 48

H.R. Rep. No. 91-1444, 91st Cong.,
2d Sess. (1970), *reprinted in* 1970
U.S.C.C.A.N. 4566 ..... 2, 3, 24

Legislation to Regulate Controlled Dangerous Substances and Amend Narcotics and Drug Laws, H.R. 17463, 91st Cong. § 201 (1970) ... 14

Purpose of Issue of Prescription,
36 Fed. Reg. 4948 (1971) 26

Purpose of Issue of Prescription,
36 Fed. Reg. 7799 (1971) 26

S. Rep. No. 105-372 *Lethal Drug Abuse Prevention Act* 105th Congress, 2d Session (1998) 7

Page

S. Rep. No. 106-299 *The Pain Relief Promotion Act*, 106th Congress, 2d Session (2000) 7

S. Rep. No. 98-225, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182... 4, 24

Other Authorities

T. Ackerman, *Poll: Many Doctors Back Assisted Suicide*, Houston Chronicle, May 3, 2001, *available at* http://www.dwd.org/fss/news/houston.asp 33

Am. Med. Women's Ass'n, *Position Statement on Physician-Assisted Suicide*, *available at* http://www.amwa-doc.org/index.cfm?objectid=242FFEF5-D567-0B25-585DC5662AB71DF9 32

A. Batavia, *The Relevance of Data on Physicians and Disability on the Right to Assisted Suicide*, 6 PSYCH. PUB. POL'Y & L. 552 (2000) 31

A. E. Chin *et al.*, *Oregon's Death with Dignity Act: The First Year's Experience*, Department of Human Resources, Oregon Health Division Center for Disease Prevention and Epidemiology, February 18, 1999 ..... 17, 29

R. Cohen-Almagor, *Euthanasia and Physician-Assisted Suicide in the Democratic World: A Legal Overview*, 16 N.Y. INT'L L. REV. 1 34

Page

D. Colburn, *Terminally Ill Opting to Starve*, The Oregonian, July 24, 2003; *available at* http://www.oregonlive.com/special/assisted_suicide/index ssf?/special/oregonian/suicide/072403.html 37

Comparative Reflections on the Belgian Euthanasia Act 2002, 11 MEDICAL L. REV. 353-376 (Autumn 2003) 34

E. J. Emanuel *et al.*, *Attitudes and Practices of U.S. Oncologists Regarding Euthanasia and Physician-Assisted Suicide*, 133 ANNALS INTERNAL MED. 527 (2000)..... 41

D. Fenn & L. Ganzini, *Attitudes of Oregon Psychologists Toward Physician-Assisted Suicide and the Oregon Death with Dignity Act*, 30 PROF. PSYCH.: RES. & PRACTICE, 235 (1999) 35

P. Ford, *World Divided on Ethics of Terri Schiavo Case*, Christian Science Monitor, Mar. 25, 2005, *available at* http://www.csmonitor.com/2005/0325/p01s04-wogi.html 34

Fourth Annual Report on Oregon's Death with Dignity Act, Department of Human Services, Office of Disease Prevention and Epidemiology, February 6, 2002 ..... 17, 37

L. Ganzini *et al.*, *Attitudes of Oregon Psychiatrists Toward Physician-assisted Suicide*, 153 AM. J. PSYCHIATRY 1469 (1996) 35

Page

L. Ganzini & S. K. Dobscha, *Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS 119 (2004) 38, 40

L. Ganzini *et al.*, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEW. ENG. J. MED. 582 (2002) 35, 37

L. Ganzini *et al.*, *Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALLIATIVE MED. 381 (2003) 35, 39

L. Ganzini *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363 (2001) 32, 35, 40

L. Ganzini *et al.*, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW ENG. J. MED. 557 (2000) 35, 39

C. Hall, *'Historic' Change as Opposition to Euthanasia Ends*, The Telegraph, July 1, 2005, *available at* http://www.telegraph.co.uk/news/mainjhtml?xml=/news/2005/07/01/neut01.xml&sSheet=/news/2005/07/01/ixhome.html 34

The Harris Poll #32, Majorities of U.S. Adults Favor Euthanasia and Physician-Assisted Suicide by More than Two-to-One, Apr. 27, 2005, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=561 31

Page

K. Hedberg *et al.*, *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 NEW ENG. J. MED. 961 (March 6, 2003) 17, 37

K. Hedberg, *Oregon's Death with Dignity Act: Three Years of Legalized Physician-Assisted Suicide*, Department of Human Services, Oregon Health Division Center for Disease Prevention and Epidemiology, February 22, 2001 .....17, 29, 36, 37

K. Jost, *Right to Die*, 15 CQ RESEARCHER 423, 428 (2005)..... 31

R. J. Kohlwes *et al.*, *Physicians' Responses to Patients' Requests for Physician-Assisted Suicide*, 161 ARCHIVES INTERNAL MED. 657 (2001) 41

Louis Finkelstein Institute for Social and Religious Research, poll conducted last week of February 2005 Reuters, Business Wire (March 3, 2005) 33

R. Lunge *et al.*, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes* (2004) *available at* http://www.leg.state.vt.us/reports/04Death/Death_With_Dignity_Report.htm 48

R. S. Magnusson, *"Underground Euthanasia" and the Harm Minimization Debate*, 32 J. L. MED. & ETHICS 486 (2004)..... 40

Page

D. E. Meier *et al.*, *A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 NEW ENG. J. MED. 1193 (1998).... 40-41

Official Results State Measure 51, Nov. 4, 1997 State Wide Special Election *available at*: http://www.sos.state.or.us/elections/nov497/other.info/m51abst.htm..... 6

T. E. Quill, MD & C. K. Cassel, MD, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138 ANNALS OF INTERNAL MEDICINE 208 (2003) 33

Seventh Annual Report on Oregon's Death with Dignity Act, Oregon Department of Human Services, March 10, 2005 *available at* http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf.....*passim*

Sixth Annual Report on Oregon's Death with Dignity Act, Oregon Department of Human Services, March 10, 2004 ..... 17, 37

A. D. Sullivan *et al.*, *Oregon's Death with Dignity Act: The Second Year's Experience,* Department of Human Services, Oregon Health Division Center for Disease Prevention and Epidemiology, February 23, 2000..... 17, 29

H. Taylor, *The Harris Poll #2, 2-to-1 Majorities Continue to Support Rights to Both Euthanasia and Doctor-Assisted Suicide*, Jan. 9, 2002, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=278 30

Page

V. P. Tilden *et al.*, *Oregon's Physician-Assisted Suicide Vote: Its Effect on Palliative Care*, 44 NURSING OUTLOOK 80 (1996)..... 39

S. Tolle *et al.*, *Characteristics and Proportion of Dying Oregonians Who Personally Consider Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS 111 (2004)..... 38

J. L. Werth, *"Assisted Suicide" versus Improved End-of-Life Care: Mutually Exclusive Decisions Or Artificial Dichotomy?* 27 DEATH STUDIES 748 (2003) 39-40

J. L. Werth & H. Wineberg, *A Critical Analysis of Criticisms of the Oregon Death With Dignity Act*, 29 DEATH STUDIES 1 (2005) 34

S. N. Whitney, MD, JD, *et al.*, *Views of United States Physicians and Members of American Medical Association House of Delegates on Physician-assisted Suicide*, 16 J. GEN. INTERNAL MED. 290 (2001)..... 32

IN THE

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No. 04-623

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Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ of Certiorari
To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR PATIENT-RESPONDENTS

OPINIONS BELOW

The opinion of the Court of Appeals, Pets. App. 1a-63a, is reported at *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004). The opinion of the District Court, Pets. App. 64a-97a, is reported at *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002).

STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004. Pets. App. 98a-99a. The petition for a writ of certiorari was filed on November 9, 2004, and was granted on February 22, 2005. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

Certain provisions of the Controlled Substances Act ("CSA") Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. §§ 801 *et seq.*), and a regulation promulgated thereunder, 21 C.F.R. § 1306.04, are set out in the Petitioners' Appendix at Pets. App. 149a-161a. Certain provisions of the Oregon Death with Dignity Act (the "Dignity Act") are set out in the Petitioners' Appendix at Pets. App. 162a-165a.

STATEMENT OF THE CASE

Congress enacted the CSA as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. As this Court recently recognized, the CSA was designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Gonzales v. Raich*, 545 U.S. ___, 125 S. Ct. 2195, 2203 (2005) (footnote omitted); *see also* H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. (1970) ("HR 91-1444"), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567, 9th Cir. SER at 3[1] (noting that the CSA's principal purpose was "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States"). As the House Committee Report regarding the bill that became the CSA explained:

> The bill provides for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.

Id. at 4569, 9th Cir. SER at 5 (quoted in *United States v. Moore*, 423 U.S. 122, 135 (1975)).

The provisions of the CSA are overwhelmingly directed toward the registration requirements for individuals engaged in the manufacture, distribution and sale of scheduled drugs and the enforcement provisions for any violation. It is silent as to the regulation of the practice of medicine. Indeed, the CSA manifests Congress' intent to delegate to the States the power to register those who have legitimate dealings with controlled substances, and not any intent for the Attorney General to define how those professionals practice medicine. *See* 21 U.S.C. § 801a(1) (the need to control "illicit trafficking" of psychotropic substances); *id.* § 801(3) (legislation to address "traffic in controlled substances"); *see also Raich*, 125 S. Ct. at 2203 n.20 (citing same). The legislative history similarly confirms that Congress did not intend to regulate medical practices that are legal under state law and that have no relation to drug abuse, trafficking or diversion. *See Moore*, 423 U.S. at 135.[2]

[1] Citations to Patient-Respondents' 9th Circuit Supplemental Excerpts of Record are cited hereto as "9th Cir. SER at ___"; citations to Petitioners' Appendix to the Petition for a Writ of Certiorari are cited hereto as "Pets. App. at ___"; citations to Patient-Respondents' Appendix to its Brief in Opposition to Petition for a Writ of Certiorari are cited hereto as "Pet. Opp. App. at ___."

[2] The overwhelming majority of the remarks of various members of Congress highlight that the CSA was intended to address the problems of drug abuse and trafficking of controlled substances, and not the regulation of the practice of medicine. *See, e.g.*, 116 Cong. Rec. 977 (1970), 9th Cir. SER at 27 (Sen. Dodd) (the CSA "is intended to deal with the control of the illicit drug traffic, the diversion of legal drugs into illegal and non-medical channels, and the enforcement of the drug laws by the Justice Department"); *id.* at 1690, 9th Cir. SER at 30 (Sen. Tower) (the CSA addresses "drugs legally produced in this country [that] are diverted through illicit channels to non-medical use" and "reduce the volume of drugs illegally produced, diverted and smug-

Congress amended the CSA in 1984 when it adopted the Dangerous Drug Diversion Control Act (the "DDDCA"). As its title reflects, this legislation was aimed squarely at the diversion of drugs out of the closed medical system:

> [These amendments] are intended to address the severe problem of diversion of drugs of legitimate origin into the illicit market. Diversion of legally produced drugs into illicit channels is a major part of the drug abuse problem in the United States.

S. Rep. No. 98-225, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3442, 9th Cir. SER at 80; *see also Trawick v. DEA*, 861 F.2d 72, 75 (4th Cir. 1988) (noting the 1984 Act "specifically targeted dispensing practitioners who abused their registrations by diverting legitimate, prescription drugs to illegitimate uses").[3]

gled"); *id.* at 33,297, 9th Cir. SER at 31 (Rep. Madden) ("Title II of the bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal."); *id.* at 33,311, 9th Cir. SER at 33 (Rep. Clancy) (the CSA is intended to "significantly reduce the widespread diversion of drugs out of legitimate channels into illicit markets"); *id.* at 33,317, 9th Cir. SER at 35 (Rep. Monagan) (Under the CSA, "stringent registration requirements will be imposed upon manufacturers, wholesalers, and retailers in the legitimate drug distribution chain to prevent the diversion of legally produced drugs into the illicit drug traffic.").

[3] The DDDCA was enacted to address limitations in various state laws dealing with the diversion of drugs. *See* S. Rep. No. 98-225, 1984 U.S.C.C.A.N. at 3448, 9th Cir. SER at 86; *see also id.* 3448-3449, 9th Cir. SER at 86-87. The remarks of House and Senate members regarding the DDDCA establish that Congress adopted this legislation to prevent the diversion of legitimate drugs into illicit markets. *See, e.g.*, 130 Cong. Rec. 1,586 (1984), 9th Cir. SER at 90 (Sen. Laxalt) ("Current

For the last several decades, and almost entirely without reference to the CSA, the nation has been grappling with complex issues of health policy and individual liberty at the end of life. Modern medicine can now extend the dying process to a point that many terminally ill patients find intolerable. A pair of cases filed in the early 1990s, one in the State of New York and the other in the State of Washington, sought recognition that mentally competent, terminally ill patients have a right protected under the U.S. Constitution's guarantees of liberty and equality to choose to hasten their impending deaths by obtaining medications prescribed by their physicians for this purpose. These cases began to wind their ways through the federal judiciary. *See, e.g., Quill v. Koppell,* 870 F. Supp. 78 (S.D.N.Y. 1994); *Glucksberg v. Washington,* 850 F. Supp. 1454 (W.D. Wa. 1994).

In the legislative arena, in November 1994, Oregon voters approved the Oregon Death With Dignity Act (the "Dignity Act"). However, implementation of the Dignity Act was delayed by litigation until February of 1997. *See Lee v. Oregon*, 107 F.3d 1382, 1386, 1392 (9th Cir. 1997).

law—the Controlled Substances Act of 1970—provides necessary regulation of manufacturers and distributors, but it does not adequately cover the practitioner level of the distribution chain, the level at which 80 to 90 percent of current diversion of drugs into illicit markets takes place."); *id.* at 25,849, 9th Cir. SER at 91 (Rep. Sawyer) ("Diversion is the connotation for the various means by which legitimate medical controlled substances are diverted from proper use to improper use. Invalid prescriptions and pharmacy robberies are two types of retail level diversion. While much of the drug enforcement focus has been placed on the interdiction of improperly imported substances, the problem of domestic diversion has quietly grown to staggering proportions."). It was the DDDCA that added the "inconsistent with the public interest" revocation provisions of § 824(a)(4); this provision is discussed *infra* at Section II.C of the Argument.

Four months later, on June 27, 1997, this Court issued its decisions in *Washington v. Glucksberg*, 521 U.S. 702 (1997), and *Vacco v. Quill*, 521 U.S. 793 (1997). In *Glucksberg*, the Court concluded:

> Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.

521 U.S. at 735. Concurring with the Court, Justice O'Connor explained:

> There is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure. * * * [T]he * * * challenging task of crafting appropriate procedures for safeguarding * * * liberty interests is entrusted to the "laboratory" of the States * * * in the first instance.

Id. at 737 (O'Connor, J., concurring) (quotation marks omitted) (quoting *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 292 (1990) (O'Connor, J., concurring)).

In November 1997, the citizens of Oregon once again voted on the Dignity Act, with 60% voting in favor of it. *See Official Results State Measure 51*, Nov. 4, 1997 State Wide Special Election *available at*: http://www.sos.state.or.us/elections/nov497/other.info/m51abst.htm; 9th Cir. SER at 103.

In response to requests by members of Congress in late 1997, including then-Senator Ashcroft, Attorney General Reno analyzed the question of whether practitioners acting

in accordance with the Dignity Act contravened the CSA. On June 5, 1998, Reno answered, definitively, "No":

> The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

Letter from U.S. Attorney General Janet Reno to Henry J. Hyde (June 5, 1998) ("Reno Letter"), Pet. Opp. App. at 50a. Reno explained that "[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." *Id.* at 52a.

Later that year the Dignity Act's Congressional opponents, again including then-Senator Ashcroft, introduced the Lethal Drug Abuse Prevention Act of 1998 (the "LDAPA"), *see* S. Rep. No. 105-372, *Lethal Drug Abuse Prevention Act*, 105th Congress, 2d Session (1998), 9th Cir. SER at 120, but it failed to reach the floor of the House or the Senate. *See* H.R. 4006 and S. 2151, 105th Congress (1998). They then introduced the Pain Relief Promotion Act of 1999 (the "PRPA"). *See* S. Rep. No. 106-299, *The Pain Relief Promotion Act*, 106th Congress, 2d Session (2000), 9th Cir. SER at 173. The PRPA passed the House in 1999 and made it out of the Senate Judiciary Committee in 2000, but failed to reach a vote on the floor of the Senate. *See* H.R. 2260 and S. 1272, 106th Congress (1999). Both the LDAPA and the PRPA would have expanded the scope of the CSA to nullify the Dignity Act. Both failed.

Following the election of 2000, President Bush appointed Ashcroft to be U.S. Attorney General. Understandably concerned, Oregon's Attorney General wrote to Ashcroft, asking that Oregon be consulted in the event that the Department of Justice decided to reconsider the relationship between the CSA and the Dignity Act. Letter from Hardy Myers, Oregon Attorney General, to John Ashcroft, United States Attorney General (February 2, 2001), Pet. Opp. App. at 55a. In response, Ashcroft stated that he "would be happy to include [Oregon's] views" if he ever revisited the matter. Letter from Lori Sharpe, Director and Advisor to the U.S. Attorney General, to Hardy Myers, Oregon Attorney General (April 17, 2001), Pet. Opp. App. at 58a.

However, on November 6, 2001, without consulting or even notifying Oregon, Ashcroft announced that he had reversed his predecessor's decision. Under his new interpretation of the CSA—even without passage of the LDAPA or the PRPA—prescribing controlled substances under the Dignity Act would be a violation of the CSA and would result in the revocation of a practitioner's license. *See* 66 Fed. Reg. 56,607 (November 9, 2001), Pets. App. at 100a (the "Directive").

Respondents then filed this action. The District Court found that the Directive violated the CSA and permanently enjoined it. *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002). Pets. App. at 64a. The Court of Appeals, exercising its own jurisdiction to review the challenge to the Directive, held that the Directive "is unlawful and unenforceable because it violates the plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority." *Oregon v. Ashcroft*, 368 F.3d 1118, 1120 (9th Cir. 2004), Pets. App. at 1a. This writ followed.

ARGUMENT

I. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference.

Petitioners contend that the Court of Appeals erred by failing to accord the Directive proper deference. Yet they provide no support for this assertion of executive power.[4]

An agency's action is subject to distinct standards of review based upon whether it interprets a statute or its own regulation. Some actions, as here, implicate both. Although the Directive states that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," Pets. App. at 102a, Section 1306.04 does not authorize the Attorney General to suspend a health care provider's DEA registration. Thus, the Directive also relied upon the CSA itself in addition to Section 1306.04: "Such conduct by a physician * * * may render his registration * * * subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4)." *Id.* (quotation marks

[4] The question of the deference due Petitioners' interpretation of the CSA arises only if this Court finds that it cannot divine Congress's intent based upon its own analysis. *See General Dynamics Land Systems, Inc. v. Cline*, 540 U.S. 581, 600 (2004) ("Even for an agency able to claim all of the authority possible under *Chevron*, deference to its statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent.") (citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446-48 (1987)); *see also* Resp. Oregon Br. at 30-31. For the reasons set forth by Respondent State of Oregon, Resp. Oregon Br. at 34-42, Patient-Respondents submit that the CSA is unambiguous and does not include the necessary clear statement of intent to displace the states' traditional regulation of medicine. (Patient-Respondents endorse and adopt the positions set forth by the State of Oregon; this brief is intended to complement the State's brief.) That said, the following discussion assumes that this Court does reach the question of deference and must decide whether, between the competing interpretations, the Petitioners' view is entitled to greater deference than that of the Respondents.

omitted). Petitioners therefore must defend Ashcroft's interpretation of both the statutory and regulatory provisions under this Court's separate standards.

A. Ashcroft's Interpretation of the CSA Is Not Entitled to Heightened Deference Under *Chevron*.

An agency's interpretation of a statute is entitled to one of two levels of deference—either the higher level of deference laid out by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or the lower level of respect described in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Until petitioning this Court, Ashcroft did not claim *Chevron* deference; indeed, he expressly relied upon *Skidmore* below. *See, e.g.*, Br. for Appellants, 2002 WL 32157019 at 22 and 38-40 (Sept. 23, 2002). And, while Petitioners now claim *Chevron* deference in Section I.B.2 of their opening brief, they do not explain why it is warranted. *See* Pets. Br. at 21.

As a threshold matter, an agency's interpretation of a statute is entitled to *Chevron* deference only if it "appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). If an agency passes the first test,[5] it still must establish the right to *Chevron* deference rather than *Skidmore* respect. This Court's recent decisions in

[5] Petitioners simply assume that Ashcroft was exercising authority accorded by the CSA when promulgating the Directive. As with the threshold question of whether it is necessary to reach a deference analysis, Respondent State of Oregon's Brief details why this is inaccurate. *See* Resp. Oregon Br. at 21-25. However, for the purposes of this discussion, it may be assumed that Ashcroft did possess such authority.

Barnhart v. Walton, 535 U.S. 212 (2002), and *Mead* identified eight factors to consider in selecting between *Chevron* and *Skidmore*: (1) the formality of interpretation; (2) the interstitial nature of the legal question; (3) the expertise of the agency; (4) the importance of the question to the administration of the statute; (5) the complexity of that administrative scheme; (6) the duration of consideration; (7) the consistency of interpretation; and (8) the care of consideration. *See Barnhart*, 535 U.S. at 222; *Mead*, 533 U.S. at 231-34; *see also James v. Von Zemenszky*, 301 F.3d 1364, 1365-66 (Fed. Cir. 2002) (discussing same). Petitioners neither analyzed these factors nor even cited *Barnhart* or *Mead*.

1. The *Mead* and *Barnhart* factors preclude *Chevron* deference.

a. *Interpretive rules such as the Directive are not entitled to Chevron deference. Chevron* deference is generally withheld from informal agency actions such as interpretive rulings. *Barnhart*, 535 U.S. at 222 ("[W]hether a court should give [*Chevron*] deference depends in significant part upon the interpretive method used * * *."). As this Court explained, interpretive rules

> are not entitled to the same deference as norms that derive from the exercise of [an agency's] delegated lawmaking powers. Instead, interpretations contained in formats such as opinion letters are 'entitled to respect' under [the] decision in *Skidmore v. Swift & Co.*, but only to the extent that those interpretations have the power to persuade.

Christensen v. Harris County, 529 U.S. 576, 587 (2000) (quoting *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991)) (citations and quota-

tion marks omitted); *see also Mead*, 533 U.S. at 232 ("[I]nterpretive rules * * * enjoy no *Chevron* status as a class."). Indeed, *Chevron* itself explained that it applied only to "legislative regulations." *Chevron*, 467 U.S. at 844.

In *Mead*, this Court recognized that "the overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication." *Mead*, 533 U.S. at 230 n.12. The Court then cited to twenty-seven separate examples of its own application of *Chevron* deference to formal agency actions, and only one to an informal rulemaking. *Id.* at 230-31 & nn.12-13.[6] Just last year this Court again refused to apply *Chevron* deference in a situation similar to the one here. *See Alaska Dept. of Environmental Conservation v. EPA*, 540 U.S. 461, 124 S. Ct. 983, 1001 (2004) (ruling an EPA "internal guidance memoranda * * * d[id] not qualify for the dispositive force described in *Chevron*") (citing *Christensen*, 529 U.S. at 587, and *Mead*, 533 U.S. at 234).

As Petitioners admit, the Directive is an "interpretive rule." *See* Pets. Br. at 8 ("On November 9, 2001, the Attorney General published an interpretive rule * * * that adopted the analysis of the OLC Memorandum."). The burden therefore falls to Petitioners to establish that the Directive is entitled to heightened deference under *Chevron*. They have not even attempted to meet this burden.

b. *Physician-assisted dying is not an interstitial gap in the CSA*. This Court, in *Barnhart*, accepted that an agency might receive *Chevron* deference where it employed informal rulemaking to plug a small hole in a regulatory scheme. *See Barnhart*, 535 U.S. at 214-215, 223-224 (accepting the Social Security Administration's definitions of "inability" and "expected to last," notwithstanding the informal method used to arrive at those definitions). Such is not the case here, as there was no such interstitial gap in the CSA with regard to physician-assisted dying. Indeed, there is no evidence that Congress ever considered the practice of physician-assisted dying when it adopted the CSA.

c. *The Department of Justice is not an expert in the field of medicine*. The Department of Justice is neither the Department of Health and Human Services nor the Surgeon General's Office, two federal agencies concerned with matters of medical policy. *See Oregon v. Ashcroft*, 368 F.3d at 1130 (noting that "that the Attorney General has no specialized expertise in the field of medicine"). In fact, the Attorney General was specifically denied the authority to make medical and scientific decisions under the CSA.

The original draft of the CSA would have given the Attorney General the unchecked authority to make medical and scientific decisions regarding drug control:

> Attorney General * * * may, upon his own motion * * * add, delete, or reschedule a substance as a controlled dangerous substance. Before so doing, the Attorney General shall request the advice in writing from the Secretary of Health, Education, and Welfare and from the Scientific Advisory Committee [appointed by the Attorney General] * * *. After considering the above factors, the Attorney General shall make findings with respect thereto and shall issue an order controlling the substance if he finds that the substance has a potential for abuse or that control is required * * *.

[6] The *Barnhart* Court did not find any new examples. The lone case cited by the *Mead* and *Barnhart* Courts wherein an informal agency action received *Chevron* deference was *NationsBank of N.C., N.A. v. Variable Annuity Life Insurance Co.*, 513 U.S. 251 (1995), which hinged upon the extreme deference granted to the Comptroller of the Currency under longstanding precedent. *See Mead*, 533 U.S. at 231 n.13.

Legislation to Regulate Controlled Dangerous Substances and Amend Narcotics and Drug Laws, H.R. 17463, 91st Cong. § 201 (1970), 9th Cir. SER at 45-46. In other words, under the provision as originally written, the Attorney General had to request advice, but there was no requirement that he follow it.

After the scientific and medical communities expressed concern, and following lengthy testimony from numerous medical professionals and organizations,[7] Congress adopted the present version of the CSA, which places responsibility for such decisions in the Department of Health and Human Service:

[7] For example, the Chairman of the AMA's Committee on Alcoholism and Drug Dependence testified as follows:

> The bill gives the Attorney General authority to control dangerous substances. This authority includes the scheduling of drugs. * * *
>
> There are several considerations which go into a decision to control a drug, and the bill, in fact, lists nine of them. Many of these considerations are exclusively medical and scientific in nature * * *. Others are exclusively in the area of police power * * * Still others involve both medico-scientific and enforcement aspects * * *.
>
> We believe the Secretary of HEW is in a favorable situation to provide for the necessary basic studies and to evaluate recommendations for classifying drugs. He should have the final decision on the medical and scientific aspects of scheduling, and scheduling should be predicated on his decision.

91st Cong. at 358, 9th Cir. SER at 48 (statement of Dr. Henry Brill, Chairman, Committee on Alcoholism and Drug Dependence of American Medical Association's Council on Mental Health). Similarly, a representative of the Pharmaceutical Manufactures Association testified: "We feel very strongly that determinations and ultimate decision on scientific and medical matters must be made by qualified medical and scientific personnel on the basis of medical and scientific evidence." *Id.*, at 437, 9th Cir. SER at 53 (statement of Mr. Bruce J. Brennan, Vice President and General Counsel, Pharmaceutical Manufacturers Association).

> The Attorney General shall, before initiating proceedings [to Schedule a drug], request from the Secretary [of Health and Human Services] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled * * *. The recommendations of the Secretary to the Attorney General *shall be binding on the Attorney General as to such scientific and medical matters*, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.

21 U.S.C. § 811(b), Pet. Opp. App. at 1a (emphasis added).

If Congress withheld from the Attorney General the lesser power to make medical and scientific decisions as to the scheduling of drugs, Congress certainly did not intend to grant the Attorney General the greater power to decide—on a national basis—what constitutes a legitimate medical practice.

d. *Federal prohibition of state-regulated physician-assisted dying does not impact the CSA's administration.* As the courts' analyses below make clear, the CSA was not intended to address the situation covered by the Dignity Act. Pets. App. at 13a-14a & n.7; Pets. App. at 89a-92a. Rather, "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Raich*, 125 S. Ct. at 2203 (footnote omitted).

e. *The Dignity Act does not make the CSA's administrative scheme more complex.* The CSA's administrative

scheme is made no more complex by protecting Oregon's medical practitioners from prosecution in the limited circumstances of the Dignity Act. Indeed, the Directive has the opposite effect. If it were implemented, DEA agents would be required to determine a doctor's intent, *post-facto*, whenever a patient died after obtaining a prescription from that patient's doctor.

f. *There is no evidence that the Attorney General considered the Directive for a substantial period of time*. One cannot tell how long Ashcroft considered his position, as the process occurred behind closed doors.

g. *The Directive is inconsistent with another Attorney General's prior interpretation*. The Directive is inconsistent with the Department's prior definitive position. In 1998, Attorney General Reno "concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Reno Letter, Pet. Opp. App. at 53a. The Ashcroft Directive is an improper reversal of this rule.

h. *The Attorney General did not consider the matter with care*. Ashcroft's involvement with the legal issues implicated at the end of life traces back to his role as the Governor of Missouri during the lead-up to *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990). Upon entering the Senate, he assumed a leading role in congressional efforts to amend the CSA to prohibit the practice of physician-assisted dying. *See Oregon v. Ashcroft*, 368 F.3d at 1123 & n.4.

After being appointed Attorney General in 2000, Ashcroft reversed his predecessor's decision. This process took place under a cloak of secrecy and relied almost exclusively upon

pre-*Glucksberg* materials and analysis. Neither the OLC Memo nor the Directive indicate that Ashcroft considered the available data that Oregon had compiled from three years of experience with the Dignity Act.

By November 6, 2001, teams of epidemiologists from both the federal and Oregon governments had prepared three annual reports based upon the experience of Oregon's doctors and patients.[8] Given the parade-of-horribles the Dignity Act's opponents espoused in opposing its passage—a litany which the OLC Memo repeated, *see* OLC

[8] There are now a total of seven annual reports on Oregon's experience with the Dignity Act: A. E. Chin *et al.*, *Oregon's Death with Dignity Act: The First Year's Experience*, Department of Human Resources, Oregon Health Division Center for Disease Prevention and Epidemiology, February 18, 1999 ("First Annual Report"), 9th Cir. SER at 281; A. D. Sullivan *et al.*, *Oregon's Death with Dignity Act: The Second Year's Experience*, Department of Human Services, Oregon Health Division Center for Disease Prevention and Epidemiology, February 23, 2000 ("Second Annual Report"), 9th Cir. SER at 329; K. Hedberg, *Oregon's Death with Dignity Act: Three Years of Legalized Physician-Assisted Suicide*, Department of Human Services, Oregon Health Division Center for Disease Prevention and Epidemiology, February 22, 2001 ("Third Annual Report"), 9th Cir. SER at 361; *Fourth Annual Report on Oregon's Death with Dignity Act*, Department of Human Services, Office of Disease Prevention and Epidemiology, February 6, 2002 ("Fourth Annual Report"), 9th Cir. SER at 384; K. Hedberg *et al.*, *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 NEW ENG. J. MED. 961 (March 6, 2003) ("Fifth Annual Report"), Pet. Opp. App. at 46a; *Sixth Annual Report on Oregon's Death with Dignity Act*, Oregon Department of Human Services, March 10, 2004 ("Sixth Annual Report"), Pet. Opp. App. at 11a; *Seventh Annual Report on Oregon's Death with Dignity Act*, Oregon Department of Human Services, March 10, 2005 ("Seventh Annual Report"), *available at* http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf. All of these reports can be accessed in .pdf format on the Oregon Department of Human Services' website, *available at* http://egov.oregon.gov/DHS/ph/pas/ar-index.shtml.

Memo at 10 n.17, Pets. App. at 122a-124a—the most probative evidence on the question of whether physician-assisted dying *actually* poses a threat to the public is the substantive data gathered pursuant to the Dignity Act.[9] Yet this wealth of information was not cited once by the OLC Memorandum nor the Directive, and there are no findings or analyses anywhere that purport to show how these data evidence the alleged threat to the public interest. Such studied ignorance is a failure to consider the matter with care, and by itself grounds for striking the Directive. *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983) ("*MVMA*") ("[A]n agency rule would be arbitrary and capricious if the agency * * * entirely failed to consider an important aspect of the problem.").

The parallels between *MVMA* and the present case are striking. The *MVMA* Court reviewed the National Highway Traffic Safety Administration's ("NHTSA") 1982 rescission of a 1977 regulation, which regulation would have required passive restraints—airbags or automatic seatbelts—in all cars made after 1984. *Id.* at 38-39. The 1982 rescission explained that the NHTSA was no longer able to find, as it had in 1977, that the requirement would produce any significant benefit. In 1977, the agency assumed a 60/40 split of airbags to automatic seatbelts. By 1981, however, it was clear that automobile manufacturers would install automatic seatbelts in 99% of the new cars, and that most automatic seatbelts could easily be detached. Thus, reasoned the NHTSA, there was no rationale for requiring either type of restraint. *Id.*

[9] These data show not only that regulated physician-assisted dying does not pose a threat to the public, they suggest that the practice serves the public interest. *See* Section II.B, *infra*.

This Court disagreed. Given the admitted effectiveness of airbags, the "logical response" to the industry's shift would be to require airbags. *Id.* at 48. "[T]his alternative way of achieving the objectives of the Act should have been addressed and adequate reasons given for its abandonment. But the agency * * * did not even consider the possibility in its 1981 rulemaking. Not one sentence of its rulemaking statement discusses the airbags-only option." *Id.* Continuing, the Court stated:

> There are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such * * * practice * * *. Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.

Id. (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962)) (emphasis in original).

Just as in *MVMA*, the Oregon data was not cited once in the OLC Memo, nor is there any evidence that the data were considered behind the Department's closed doors. Neither was Oregon's evidence mentioned in the Directive. There are no findings or analysis anywhere regarding how this data relates to the claimed threat to the public interest. Thus, just as in *MVMA*, this Court should not accord Ashcroft's interpretation deference.

In sum, all of the factors laid out in *Barnhart* and *Mead* indicate that the Directive is not entitled to *Chevron* deference. At most it warrants only *Skidmore* respect.

2. Ashcroft's interpretation is entitled to little respect under *Skidmore*.

Under *Skidmore*, an agency's interpretation of a statute may be entitled to respect, but the value thereof "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade * * * ." *Skidmore*, 323 U.S. at 140; *see also Christensen*, 529 U.S. at 587 (noting that, under *Skidmore*, interpretations are due respect "only to the extent that those interpretations have the power to persuade") (quotes and citation omitted). Ashcroft's interpretation fails the *Skidmore* criteria—which Petitioners did not analyze—and, as such, was given the proper amount of respect by the courts below.

a. *Ashcroft did not thoroughly consider the matter.* Although Ashcroft told Oregon's Attorney General that Ashcroft "would be happy to include [Oregon's] views" if he ever revisited the CSA and physician assisted-dying, he neither informed Oregon of the reconsideration nor included its views. Letter from Sharpe to Myers (April 17, 2001), Pet. Opp. App. at 58a. Neither did he consider any of the data gathered during the first four years of the Dignity Act's existence. As the District Court below observed, by "ignor[ing] his earlier promise to the Oregon Attorney General to ascertain Oregon's views," Ashcroft "lost the opportunity to evaluate carefully the scientifically conducted epidemiological studies of the Oregon Act, and the

excellent analysis of the multiple issues as set forth in the briefs submitted by [Respondents] in these proceedings." *Oregon v. Ashcroft*, 192 F. Supp. 2d at 1083.

b. *Ashcroft's legal reasoning lacks merit.* The only legal precedent cited in the Ashcroft Directive is *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). Pets. App. at 101a (citing same). Yet Petitioners abandoned this authority in the district court and mentioned it only in passing in the Court of Appeals. *See Oregon v. Ashcroft*, 192 F. Supp. 2d at 1092 n.20 (noting Petitioner "abandoned the notion, espoused in the Ashcroft directive, that the Supreme Court's decision in [*Oakland Cannabis*] is somehow controlling on the issues presented here") (citation omitted), Pets. App. at 94a. Petitioners' inconsistent reliance upon *Oakland Cannabis* is not surprising, as the sole holding therein was that "medical necessity is not a defense to manufacturing and distributing marijuana." 532 U.S. at 494. The doctrine of medical necessity is not at issue here, nor are Schedule I substances. Schedule I substances are those which have been determined to have "no currently accepted medical use," whereas those prescribed in accordance with the Dignity Act are Schedule II substances which do. *See* 21 U.S.C. §§ 812 (b)(1) and (2); *see generally*, *Raich*, 125 S. Ct. at 2203-04. Thus, *Oakland Cannabis* provides no support for the Directive.

c. *Ashcroft's interpretation is inconsistent with previous interpretations.* Lastly, as noted above, Ashcroft's interpretation conflicts with that of his predecessor, Attorney General Reno, who "concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon Law." Reno Letter, Pet. Opp.

App. at 53a; *see, Hall v. EPA*, 273 F.3d 1146, 1156 (9th Cir. 2001) (refusing to defer to an "interpretation advanced [by the E.P.A. that] does not fit with prior interpretations").

Based upon these factors, Ashcroft's interpretation of the CSA should receive no more respect than an ordinary party's.

B. Ashcroft's Interpretation of Section 1306.04 Is Not Entitled to *Seminole Rock* Deference.

Just as with its power to interpret statutes, an agency's power to interpret its regulations is neither unbounded nor unchecked. Courts "are not obliged to stand aside and rubberstamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *NLRB v. Brown*, 380 U.S. 278, 291 (1965). Instead, under *Seminole Rock*, such interpretations must be struck if "plainly erroneous or inconsistent with the regulation." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *see Norfolk Southern Railway, Co. v. Shanklin*, 529 U.S. 344, 356 (2000) ("Although generally an agency's construction of its own regulations is entitled to substantial deference, no such deference is appropriate here. Not only is the [agency's] interpretation inconsistent with the text of [the rule], but it also contradicts the agency's own previous construction * * *.") (citations omitted). Although Petitioners cite certain cases from the *Seminole Rock* line of precedent, they again simply assume deference without analysis. *See* Pets. Br. at 21.

1. The Ashcroft Directive brings Section 1306.04 too close to the constitutional line.

Ashcroft's interpretation of Section 1306.04 effectively federalizes the practice of medicine, and thus pushes the CSA too close to a constitutional line over which Congress was careful not to step. *See, e.g., Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless construction is plainly contrary to the intent of Congress.").[10] The issue here is not whether Congress *could* federalize control of the practice of medicine. Rather, it is whether Congress *did* federalize control of the practice of medicine, and in doing so gave a *clear statement* of its intent to do so. *See Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173-74 (2001) ("*SWANCC*") (refusing to analyze several constitutional questions where there was no clear statement from Congress that Congress intended to

[10] Section 1306.04 is a regulation rather than a statute. However, the canon of constitutional avoidance still applies. The "judiciary is the final authority on issues of statutory construction," *Chevron*, 467 U.S. at 843, and, of course, an agency may not assume powers by regulation that were not granted to it by statute. *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988) (an "agency's power to promulgate legislative regulations is limited to the authority delegated by Congress"); *accord La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act * * * unless and until Congress confers power upon it."). Thus, the judiciary is also the final authority on whether an agency's interpretation of a regulation has stretched it beyond its permissible scope, particularly where the agency's interpretation raises constitutional issues.

alter "the federal-state framework by permitting federal encroachment upon a traditional state power").[11] As is explained more fully in the brief of Respondent State of Oregon, there is no such clear statement in the CSA. In the absence of a clear statement from Congress authorizing the Attorney General to assume control over the practice of medicine, Ashcroft's interpretation is "plainly erroneous." *Seminole Rock*, 325 U.S. at 414.

2. The Ashcroft Directive pushes Section 1306.04 beyond the boundaries of the CSA.

Ashcroft's interpretation of Section 1306.04 exceeds the CSA's limited mandate to combat prescription drug abuse and addiction. *See* 21 U.S.C. § 801(2)-(6); Pub. L. No. 91-513, 84 Stat. 1236 (preamble); S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44, 9th Cir. SER at 80; H.R. Rep No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 9th

[11] This Court and others have long recognized "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see also, e.g., Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975) ("We recognize that the States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health."); *cf. Cruzan*, 497 U.S. at 284 (recognizing the States' right to govern end-of-life decisions); *Bristol Myers Squibb v. Shalala*, 91 F.3d 1493 (D.C. Cir. 1996) (noting that the Food Drug and Cosmetic Act does not allow the FDA to regulate how a physician prescribes a medication once approved); *see generally* Resp. Oregon Br. at 27-47.

Cir. SER at 2. To the extent that federal regulation of controlled substances does impact medical care, this Court has, when addressing the matter, seen no role for the Attorney General in determining the appropriate methods of medical practice under Section 1306.04. *See United States v. Moore*, 423 U.S. at 144 (recognizing decisions regarding "the appropriate methods of professional practice" are entrusted to what is now the Secretary of Health and Human Services) (citation omitted). While the 1984 amendments to the CSA extended the Attorney General's authority over federal registration of practicing physicians, the DDDCA neither impacted Section 1306.04 nor provided the Attorney General the authority to determine the scope of legitimate medical practice. Indeed, Section 1306.4 long *preceded* these amendments and thus clearly was not adopted to implement them.

3. Section 1306.04 was not intended to federalize the practice of medicine.

An agency must have some regulatory scheme in mind when it promulgates a rule and may not later depart from such scheme without promulgating new rules. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (holding a court should not defer to an agency's interpretation where an "alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation") (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988)); *see also Caruso v. Blockbuster-Sony Music Entertainment Centre*, 193 F.3d 730, 737 (3d Cir. 1999) ("An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning.") (citation

omitted). Yet this is exactly what Ashcroft attempted to do by reinterpreting a thirty-year-old regulation to preempt the states' traditional role as the regulators of the medical profession within their borders.

In 1971, the Bureau of Narcotics and Dangerous Drugs published notice of the "Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970." *Purpose of Issue of Prescription*, 36 Fed. Reg. 4948 (1971), Pet. Opp. App. at 3a-4a. The proposed regulation included no official commentary and almost went unnoticed. The only public comment was summarized as follows: "The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § [1306.04] to determine the legitimacy of a prescription. The language has been revised to require knowledge." *Comments and Objections to Part 306*, 36 Fed. Reg. 7777 (1971), Pet. Opp. App. at 5a-7a. The regulation was adopted substantially unchanged and has since remained untouched and largely unconstrued. *Purpose of Issue of Prescription*, 36 Fed. Reg. 7799 (1971), Pet. Opp. App. at 8a-9a.

Neither the regulation itself nor its lone public comment even hinted at Ashcroft's expansive interpretation. If it was intended as Ashcroft later interpreted it—*i.e.*, to usurp the states' traditional role as the regulators of the medical profession[12]—the proposed regulation should have been accompanied by agency commentaries and would have prompted untold hundreds of public comments from medical groups and the states. Moreover, it is unlikely that a shift of this magnitude in the role of the states within our federal system would have been achieved by means of a

[12] *See* n.11, *supra*.

single regulation, routinely promulgated amidst many others. The obvious conclusion is that the Bureau did not intend to federalize the field of medicine. *Thomas Jefferson Univ.*, 512 U.S. at 512.

Moreover, under the CSA in 1971, physicians were entitled to distribute controlled substances so long as they complied with state law, and *only* state law. *See* Pub. L. No. 91-513, 84 Stat. 1253, 1255 (§§ 303(f), 304(a)). Authorization to prescribe drugs under the CSA at that time turned on the decisions of state licensing and law enforcement authorities. *See id.* Given the statutory boundaries of the CSA as it existed in 1971, neither Congress nor the Attorney General could have intended Section 1306.04 to give the Attorney General the power to impose a uniform federal standard of medical practice. If Section 1306.04 could not have been read to federalize the practice of medicine in 1971, it cannot be interpreted to go so far in 2001. *Thomas Jefferson Univ.*, 512 U.S. at 512.

4. The Ashcroft Directive is inconsistent with the Department of Justice's prior interpretation.

Lastly, the Ashcroft Directive warrants no deference because it is contrary to Attorney General Reno's 1998 interpretation of the same regulation. *See Norfolk S. Railway Co.*, 529 U.S. at 356 (striking agency's interpretation where it was inconsistent with prior construction). As this Court recently wrote in an analogous situation, "[a]lthough generally an agency's construction of its own regulations is entitled to substantial deference, no such deference is appropriate here. Not only is the [agency's] interpretation inconsistent with the text of [the regulation], but it also contradicts the agency's own previous construction * * * ."

Id. (citation omitted); *see also SWANCC,* 531 U.S. at 168 (noting that the agency interpretation before the Court reversed the agency's prior interpretation of the same rule, yet the agency had "put forward no persuasive evidence that the [agency] mistook Congress' intent" the first time); *Hall*, 273 F.3d at 1156.

Given these faults, the Directive is "plainly erroneous [and] inconsistent with the regulation." *Seminole Rock*, 325 U.S. at 414. Ashcroft's interpretation of Section 1306.04 is therefore entitled to no deference.

II. Petitioners' Contention that the Directive Sets Forth the "Prevailing View" of Physician-Assisted Dying is Unsupported and Unsupportable.

Ashcroft purported to justify his conclusion that practice comporting with the Dignity Act is not a "legitimate medical purpose" by disregarding the most salient and authoritative information on the practice, and by positing the existence of supposedly monolithic opposition to it.[13] Yet both the size and the uniformity of this opposition is chimerical. Ashcroft ignored copious evidence of wide-ranging and growing support for legalization of physician-assisted dying. For at least the last two decades, a majority of the public has *favored* permitting physician-assisted dying under certain circumstances, and the proportion of the public supporting such legalization now dwarfs that of the opposition. Evidence readily available to Ashcroft in 2001 also revealed that, far from forming a consensus, the medical community is divided on the question of legalizing physician-assisted dying. Ashcroft's determination that

[13] Pets. App. at 102a (OLC Memo sets forth legal basis for the Ashcroft directive); *id.* at 113a-130a (OLC Memo's discussion of whether physician-assisted dying serves a "legitimate medical purpose").

physician-assisted dying threatened the public health and safety, even if stringently regulated by state law, is unsupported. Ashcroft did not so much as acknowledge the data in the three official reports that Oregon had published regarding its experience with physician-assisted dying since 1998.[14] These reports established that the risks forecast by opponents of the Dignity Act—such as involuntary administration of life-ending drugs, exploitation of vulnerable individuals, and the substitution of physician-assisted dying for effective pain management—had not come to pass.

Ashcroft's disregard of the Oregon data is significant not only for its arbitrariness and capriciousness; it goes to the heart of the Directive's violation of the CSA. The Directive decreed that a practitioner prescribing controlled substances for physician-assisted dying might have his or her license to prescribe controlled substances revoked under 21 U.S.C. § 824(a)(4). Pets. App. at 102a. Yet, as the Court of Appeals noted below, the Attorney General may revoke a practitioner's license as inconsistent with the public interest only if he considers *all five factors* specified in § 823(f). The Directive violates § 823(f) because it authorizes revocation without the required consideration of several of these factors and, as to the last factor, incorrectly assumes that physician-assisted dying is "conduct which may threaten the public health and safety."

As more fully discussed below, these flaws in logic and the law are fundamental and insurmountable. The permanent injunction of the Directive should be upheld.

[14] *See* Third Annual Report; Second Annual Report; First Annual Report.

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying.

The OLC Memo, on which Ashcroft relied, asserted the existence of uniform opposition to the legalization of physician-assisted dying by selectively quoting this Court's *Glucksberg* decision and *amici* briefs and law review articles opposing physician-assisted dying, and by exploring the official positions of but two medical associations. Pets. App. at 113a-130a.[15] Ashcroft adopted the OLC Memo's analysis wholesale while ignoring the abundance of data that refuted the notion of unvariegated opposition. For example, a Harris poll published just two months after the Directive found that, by 65% to 29%, a substantial majority of American adults favored legalization of physician-assisted dying for a terminally ill patient who so chooses.[16] Another group of studies published in 1996 found that between 63% and 90% of people with a terminal illness

[15] Cobbling together snippets of federal enactments other than the CSA and pronouncements of political appointees, the OLC Memo also contended that federal policy opposed legalization of physician-assisted dying. *See id.* at 119a-123a. None of these authorities, however, indicate that in enacting the CSA Congress intended to address the practice of physician-assisted dying, let alone to forbid a state from legalizing the practice. Moreover, that the federal government may not endorse physician-assisted dying does not mean that federal policy seeks to ban it.

[16] H. Taylor, *The Harris Poll #2, 2-to-1 Majorities Continue to Support Rights to Both Euthanasia and Doctor-Assisted Suicide*, Jan. 9, 2002, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=278. The report also noted that ever since Harris began asking this question in 1982, a majority of respondents had expressed their support for legalization of physician-assisted dying under these circumstances. *Id.*

supported a right to physician-assisted dying and wished to have the option available to them.[17]

Like Ashcroft, Petitioners fail to acknowledge these studies and more recent data that confirm the continued and growing public support for the legalization of physician-assisted dying. For example, a Gallup poll conducted in May 2003 found that approximately three-quarters of Americans supported physician-assisted dying for terminally ill patients,[18] and a Harris poll published in April 2005 found that 70% of Americans favor legalization of physician-assisted dying for a terminally ill patient who chooses this course.[19]

Ashcroft also ignored, and Petitioners presently ignore, evidence of the substantial and growing support for the legalization of physician-assisted dying by large segments of the medical, hospice, bioethics, health policy, and legal communities. This support was detailed in the *amici* briefs filed in support of the respondents in the *Quill* and *Glucksberg* cases in 1996.[20] Inexplicably, the OLC Memo did not

[17] A. Batavia, *The Relevance of Data on Physicians and Disability on the Right to Assisted Suicide*, 6 PSYCH. PUB. POL'Y & L., at 552-53 (2000) (citing W. Breibart et al., *Interest in Physician Assisted Suicide Among Ambulatory HIV Infected Patients*, 153 AM. J. PSYCHIATRY, 238-42 (1996), B. Trindell et al., *Attitudes to Euthanasia and Assisted Suicide in a Group of Homosexual Men with Advanced HIV Disease*, 6 J. OF ACQUIRED IMMUNE DEFICIENCY SYNDROME 1069 (1993)).

[18] K. Jost, *Right To Die*, 15 CQ RESEARCHER 423, 428 (2005).

[19] *The Harris Poll #32, Majorities of U.S. Adults Favor Euthanasia and Physician-Assisted Suicide by More than Two-to-One*, Apr. 27, 2005, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=561.

[20] *See, e.g.*, Brief of the Coalition of Hospice Professionals as Amicus Curiae for Affirmance of the Judgments Below, *Glucksberg*, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 709342; Brief of Amicus Curiae Bioethicists Supporting Respondents, *Glucks-*

mention these *amici* briefs, even as it relied heavily on *amici* briefs filed in support of the petitioners in *Quill* and *Glucksberg*.

Ashcroft also ignored other, more timely evidence of support for the legalization of physician-assisted dying in the medical community. A 2001 survey published by the *Journal of the American Medical Association* found that 51% of responding physicians in Oregon supported the Dignity Act and legalization of physician-assisted dying.[21] A nationwide survey published in 2001 in the *Journal of General Internal Medicine* found that 45% of responding physicians believed that physician-assisted dying should be legal, whereas only 34% expressed views to the contrary.[22] The American Medical Women's Association has, since 1997, supported "the right of physicians to engage in practice wherein they may provide a patient with, but not administer, a lethal dose of medication and/or medical knowledge, so that the patient can, without further assistance, end her/his life."[23] None of these views were considered by Ashcroft nor addressed in the underlying OLC memo.

berg, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 709337; Brief for Ronald Dworkin, Thomas Nagel, Robert Nozick, John Rawls, Thomas Scanlon, and Judith Jarvis Thomson as Amici Curiae in Support of Respondents, *Glucksberg*, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 708956; Brief Amicus Curiae of the American College of Legal Medicine, *Glucksberg*, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 668827.

[21] L. Ganzini, MD, *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-Life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363, 2365 (May 9, 2001).

[22] S. N. Whitney, MD, JD, *et al.*, *Views of United States Physicians and Members of American Medical Association House of Delegates on Physician-assisted Suicide*, 16 J. GEN. INTERNAL MED. 290, 292-93 (2001).

[23] Am. Med. Women's Ass'n, *Position Statement on Physician-Assisted Suicide*, *available at* http://www.amwa-doc.org/index.cfm?objectid=242FFEF5-D567-0B25-585DC5662AB71DF9.

Petitioners maintain Ashcroft's blinkered approach by ignoring recent evidence of growing support for legalization among the medical community and other professional communities. A national survey conducted in February 2005 found that 57% of physicians believe it is ethical for a physician to assist a competent, dying patient in hastening death.[24] Medical organizations increasingly are adopting a neutral stance on the legalization of physician-assisted dying.[25] These organizations include mainstream leaders in the medical community, such as the American Academy of Hospice and Palliative Medicine, the American Pharmaceutical Association, and the Oncology Nursing Society.[26] Petitioners' refusal even to acknowledge the positions of these organizations and the views of medical professionals nationwide, while repeatedly referring to the position of the American Medical Association (AMA), *see* Pets. Br. at 23-24, reveals how narrow is their focus.[27]

[24] Louis Finkelstein Institute for Social and Religious Research, poll conducted last week of February 2005 of 1,000 physicians. Reuters, Business Wire, March 3, 2005.

[25] *See, e.g.*, T. E. Quill, MD & C. K. Cassel, MD, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138 ANNALS OF INTERNAL MEDICINE 208, 208-11 (2003) (attaching appendix listing Medical Organizations with Neutral Stance on Physician-Assisted Suicide).

[26] *Id.* at 210.

[27] It bears mention that only 30% of physicians in this country belong to the AMA, *see* http://www.ama-assn.org/ama/pub/category/5105.html, and there is a well-established gulf between the views of the AMA's leadership on this issue and those of its rank-and-file. *See, e.g.*, T. Ackerman, *Poll: Many Doctors Back Assisted Suicide*, Houston Chronicle, May 3, 2001, *available at* http://www.dwd.org/fss/news/houston.asp.

Simply put, Petitioners are flat wrong when they declare that the Directive is "consistent with the prevailing legal and medical views regarding medical practice." Pets. Br. at 24.[28]

Much of the discussion concerning physician-assisted dying that is occurring within the medical and academic communities has been informed by and focused upon Oregon's experience with the Dignity Act.[29] The ethical, philosophical and medical literature has swelled with studies on physician-assisted dying. For instance, various surveys have been published documenting the experiences not only of the terminally ill, but also of doctors, psychiatrists, social workers and nurses who have had first-hand experience with physician-assisted

[28] Support for the legalization of physician-assisted dying also continues to grow outside of the United States. Physician-assisted dying has been legal in the Netherlands since 1994, and is legal now in Belgium and Switzerland as well. *See generally* R. Cohen-Almagor, *Euthanasia and Physician-Assisted Suicide in the Democratic World: A Legal Overview,* 16 N.Y. INT'L L. REV. 1 at nn.157-166 (Winter 2003); *Comparative Reflections on the Belgian Euthanasia Act 2002*, 11 MEDICAL L. REV. 353-376 (Autumn 2003). Great Britain is now considering legalizing physician-assisted dying for the terminally ill, and in June the British Medical Association dropped its opposition to legalization of the practice. C. Hall, *'Historic' Change as Opposition to Euthanasia Ends*, The Telegraph, July 1, 2005, *available at* http://www.telegraph.co.uk/news/mainjhtml?xml=/news/2005/07/01/neut01.xml&sSheet=/news/2005/07/01/ixhome.html. A recent poll found that strong public support exists in Spain for legalizing physician-assisted dying, with 60% of Spanish doctors favoring legalization. P. Ford, *World Divided on Ethics of Terri Schiavo Case*, Christian Science Monitor, Mar. 25, 2005, *available at* http://www.csmonitor.com/2005/0325/p01s04wogi.html.

[29] For an overview of the literature, *see, e.g.*, J. L. Werth & H. Wineberg, *A Critical Analysis of Criticisms of the Oregon Death With Dignity Act*, 29 DEATH STUDIES 1, 2 (2005).

dying.[30] This literature confirms that Oregon's experience has informed the debate, and actual data have debunked many of the shibboleths erected by opponents of physician-assisted dying.

B. The Data Regarding Oregon's Experience with the Dignity Act Demonstrate that Legal, Physician-Assisted Dying Poses No Threat to the Public Health and Safety.

Perhaps the Directive's most glaring omission was its complete disregard of the data set forth in the three annual reports that the Oregon Department of Human Services had issued regarding Oregon's experience with the Dignity Act. Published pursuant to state law, and written by public health experts, these reports provided a wealth of unvarnished empirical information on the practice of physician-assisted dying under the Dignity Act.[31] Their significance cannot be understated: at the time Ashcroft issued the Directive, they presented the only data regard-

[30] *See, e.g.*, L. Ganzini *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363 (May 9, 2001); L. Ganzini *et al.*, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW. ENG. J. MED. 557 (2000), 9th Cir. SER at 322; L. Ganzini *et al.*, *Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALLIATIVE MED. 381 (2003); L. Ganzini *et al.*, *Attitudes of Oregon Psychiatrists Toward Physician-assisted Suicide*, 153 AM. J. PSYCHIATRY 1469 (1996); L. Ganzini *et al.*, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEW. ENG. J. MED 582 (2002); D. Fenn & L. Ganzini, *Attitudes of Oregon Psychologists Toward Physician-Assisted Suicide and the Oregon Death with Dignity Act*, 30 PROF. PSYCH.: RES. & PRACTICE 235 (1999).

[31] Or. Rev. Stat. § 127.865, Pet. Opp. App. at 10a.

ing the experience of legal, regulated physician-assisted dying in the United States.

The Oregon reports established that legalization of physician-assisted dying, administered under the strictures of the Dignity Act, did not threaten the public health and safety. Physician-assisted dying was not being forced upon those who were uneducated, uninsured, or otherwise disadvantaged, which opponents of the Dignity Act had speculated would materialize. The Third Annual Report, published in 2001, found that college-educated patients were far more likely to choose physician-assisted dying than patients with less than a high-school degree.[32] The report also determined that all patients who availed themselves of physician-assisted dying under the Dignity Act had some form of health insurance, and almost all of them died at home; no patient died in an acute-care hospital.[33] The report further found that there was no evidence that pressure from others was a primary motivating influence among the patients who had chosen physician-assisted dying over the previous three years.[34]

The three reports also demonstrated that use of physician-assisted dying under the Dignity Act was quite limited. From 1998 through 2000, only 70 individuals in Oregon had availed themselves of physician-assisted dying, representing less than one-tenth of one percent of all deaths in the state.[35] Nor did every patient who obtained a prescription for life-ending medication use that medication: only

[32] Third Annual Report at 10, 17, 9th Cir. SER at 370, 377.

[33] *Id.* at 11, 22, 9th Cir. SER at 371, 381-382

[34] *Id.* at 14, 9th Cir. SER at 374.

[35] *Id.* at 13, 9th Cir. SER at 373.

two-thirds of the patients who had obtained such prescriptions in 2000 died from ingesting the medication.[36]

Petitioners likewise ignore the three annual reports published before issuance of the Directive, as well as the four annual reports published since. The four post-Directive reports confirm that the Dignity Act has been utilized sparingly and responsibly.[37] In the seven years since the Death with Dignity Act was implemented, only 208 persons have chosen physician-assisted dying, reflecting approximately 1 physician-assisted death in every 800 deaths in Oregon in 2004.[38] After an initial increase following the enactment of the Dignity Act, the number of persons who die annually utilizing physician-assisted dying has leveled off; in fact, the number of such deaths in 2004 actually declined from the previous year.[39] A 2003 study concluded that the number of Oregonians who died having chosen physician-assisted dying was less than half the number of Oregonians who hastened their death by refusing nutrition.[40]

In addition to there being relatively few deaths under the Dignity Act, the data indicates that the Act has been utilized responsibly. The overwhelming majority of persons

[36] *Id.* at 10, 9th Cir. SER at 370.

[37] Seventh Annual Report; Sixth Annual Report, Pet. Opp. App. at 15a; Fifth Annual Report, Pet. Opp. App. at 46a; Fourth Annual Report, 9th Cir. SER at 384.

[38] Seventh Annual Report at 12-16.

[39] *See id.*

[40] *See, e.g.*, L. Ganzini *et al.*, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEW. ENG. J. MED. 582 (2002); D. Colburn, *Terminally Ill Opting to Starve*, The Oregonian, July 24, 2003, *available at* http://www.oregonlive.com/special/assisted_suicide/index.ssf?/special/oregonian/suicide/072403.html.

dying via physician-assisted dying are white (97%), and tend to be younger, more affluent, and better educated than the average Oregon decedent.[41] In 2004, Oregonians with a baccalaureate degree or higher were 8.3 times more likely to use physician-assisted dying than those without a high school diploma.[42] In 2004, as in 2000, all patients who elected physician-assisted dying had some form of health insurance, and all but one of them died at home.[43] These data dispel the notions that legalization will result in large numbers of physician-assisted deaths or that the practice will be imposed disproportionately on the disadvantaged.[44]

Similarly, recent studies conducted on terminally ill patients belie the notion that the decision to choose physi-

[41] *See, e.g.*, Seventh Annual Report; S. Tolle *et al.*, *Characteristics and Proportion of Dying Oregonians Who Personally Consider Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS 111 (2004).

[42] Seventh Annual Report at 13, 22.

[43] *Id.* at 14, 24.

[44] *See, e.g.*, L. Ganzini & S. K. Dobscha, *Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS 119, 121 (2004) (concluding that "these data do not support a slippery slope of increasing death-hastening acts"). These concerns partly underlay this Court's opinion in *Glucksberg*, which preceded the promulgation of data pursuant to the Dignity Act. *See, e.g.*, 521 U.S. at 729-31 (state's interest in protecting life, especially among vulnerable groups, including the poor, the elderly, the disabled, and those who have mental disorders such as depression, justifies its banning assisted dying); *id.* at 732 (risk of harm greatest for those who suffer from poverty, lack of medical care, advanced age, or membership in a stigmatized group, and many of these might resort to physician-assisted dying to spare their families health care costs); *see also id.* at 787 (Souter, J., concurring) (capacity of state to protect incompetent patients subject to genuine question, creating a factual controversy not susceptible to judicial resolution).

cian-assisted dying is vulnerable to undue influence or coercion because it is motivated by mental disorders such as depression, or by a fear of pain or a wish alleviate the burden on family members. For instance, recent studies suggest that the decision to choose physician-assisted dying is consistently motivated by well-considered concerns of autonomy, identity and independence.[45] Interestingly, up to 40% of persons who requested and were prescribed lethal dosages did not actually take the medications,[46] suggesting that their decisions to request or to take the medication were not susceptible to undue influence, and that this option gives comfort to many more than those who actually make use of it.

The data from the Oregon experiment also suggest that physician-assisted dying and other, non-terminal end-of-life options, such as palliative care, are not mutually antagonistic. Rather, they form a continuous spectrum of end-of-life care alternatives available to terminally ill Oregonians.[47]

[45] *See, e.g.*, Seventh Annual Report at 16 (citing, *inter alia*, A. Sullivan *et al.*, *Legalized Physician-Assisted Suicide in Oregon—The Second Year*, 342 NEW. ENG. J. MED. 598 (2000)); *see also* L. Ganzini *et al.*, *Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALLIATIVE MED. 381 (2003); L. Ganzini *et al.*, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW ENG. J. MED. 557 (2000), 9th Cir. SER at 322); (patients choosing physician-assisted dying are generally "independent, determined and inflexible," most frequently cited reasons for choosing physician-assisted dying include loss of independence (57%); current or future concern of poor quality of life (55%), and desire to control the circumstances of death (53%)).

[46] *See* Seventh Annual Report at 12.

[47] *See, e.g.*, V. P. Tilden *et al.*, *Oregon's Physician-Assisted Suicide Vote: Its Effect on Palliative Care*, 44 NURSING OUTLOOK 80 (1996); J. L. Werth, *"Assisted Suicide" versus Improved End-of-Life Care: Mutually Exclusive Decisions Or Artificial Dichotomy*? 27

Almost 90% of patients who took lethal prescriptions pursuant to the Dignity Act were enrolled in hospice care.[48] Significantly, the Seventh Annual Report noted that "[t]he availability of [physician-assisted dying] as an option in Oregon also may have spurred Oregon doctors to address other end-of life care options more effectively."[49] It has promoted increased awareness of palliative care both amongst Oregon's physicians and general public; over three quarters of physicians reported that the legislation had prompted them to improve their knowledge of pain medication and their ability to diagnose psychiatric disorders such as depression.[50] Other studies indicate that, due to the presence of cumulative safeguards in the Dignity Act, Oregon's levels of legalized physician-assisted dying fall short of the levels of covert, illegal physician-assisted dying and outright euthanasia that occur in other states, and that legalization may actually be lowering the occurrence of such illegal practices.[51]

DEATH STUDIES 748 (2003) (reviewing THE CASE AGAINST ASSISTED SUICIDE: FOR THE RIGHT TO END-OF LIFE CARE).

[48] Seventh Annual Report at 14.

[49] *Id.* at 17.

[50] *See* L. Ganzini *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363 (2001).

[51] *See, e.g.*, L. Ganzini & S. K. Dobscha, *Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS at 121 (legalization may be causing a decrease in the rate of physician-assisted dying, possibly because its safeguards provide "substantial hurdles" and because it promotes physician intervention intervene once patients reveal their fears and concerns); R. S. Magnusson, *"Underground Euthanasia" and the Harm Minimization Debate*, 32 J. L. MED. & ETHICS 486 (2004) (legalization may prevent covert and inappropriate practice of physician-assisted dying and euthanasia, which occurs frequently in other states); D. E. Meier *et al.*,

The Oregon data, both in 2001 and the present day, demonstrate that the practice of physician-assisted dying, when conducted under a responsible regulatory framework such as that of the Dignity Act, poses no threat to the public health and safety. Ashcroft's failure to consider this most probative evidence on the question of whether a threat to the public health is present suggests ideology overriding reasoned analysis.

C. Physician-Assisted Dying Comports with the Five Statutory Factors Required by § 823(f).

Ashcroft determined that prescribing, administering, or dispensing controlled substances under the Dignity Act might "'render [a physician's] registration * * * inconsistent with the public interest' and therefore subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4)." Pets. App. at 102a. The Directive further declared that "[t]his conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted." *Id.*

Section 824(a)(4) provides that the Attorney General may suspend or revoke a physician's registration to dispense controlled substances upon a finding that the physi-

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A National Survey of Physician-Assisted Suicide and Euthanasia in the United States, 338 NEW ENG. J. MED. 1193 (1998), 9th Cir. SER at 272 (survey showing that over 3% of American physicians had written at least one lethal prescription, while almost 5% have ministered a legal injection); E. J. Emanuel *et al.*, *Attitudes and Practices of U.S. Oncologists Regarding Euthanasia and Physician-Assisted Suicide*, 133 ANNALS INTERNAL MED. 527 (2000) (Over 10% of American oncologists have assisted suicide); R. J. Kohlwes *et al.*, *Physicians' Responses to Patients' Requests for Physician-Assisted Suicide*, 161 ARCHIVES INTERNAL MED. 657 (2001) (more physicians favor assisted suicide than not).

cian "has committed such acts as would render his registration under section 823 of [title 21] inconsistent with the public interest as determined under such section * * *." 21 U.S.C. § 824(a)(4). Section 824(a)(4) thus expressly incorporates by reference § 823's standard for determining whether a physician's registration is "inconsistent with the public interest."

Subsection (f) of § 823 provides that standard. It lists five factors that the Attorney General "shall" consider in determining the public interest:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id. § 823(f). The Court of Appeals correctly noted below that consideration of *all five of these factors* is mandatory because § 823(f) provides that the five factors "*shall* be considered." *Oregon v. Ashcroft*, 368 F.3d at 1127 (quoting 21 U.S.C. § 823(f)) (emphasis in original). The OLC Memo's advice that Ashcroft could revoke or suspend a physician's registration based on "any" of these five factors contravened the plain language of the statute. *Id.* (quoting OLC Memo, Pets. App. at 110a).

Ashcroft impermissibly applied this erroneous advice. As the Court of Appeals correctly concluded, this core aspect of the directive represents a clear-cut violation of the CSA that cannot be cured.[52]

Ashcroft's decision to avoid consideration of all five factors was surely no accident. A review of the practice of lawful, regulated physician-assisted dying demonstrates that it comports with the five factors—both those Ashcroft purported to consider and those he ignored—and, thus, cannot be the basis for revoking a physician's license to prescribe controlled substances. The first factor is satisfied if a physician complies with the regulations of the law of

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[52] Petitioners contend that the Directive does not implicate § 823(f) because that section "applies only to actions by the Attorney General to deny or revoke a CSA registration" and the Directive "is not such a denial or revocation" but "an interpretation of the *substantive* provisions of the [CSA] * * *." Pets. Br. at 49 (emphasis in original). Petitioners' argument does not square with the plain language of the Directive. Ashcroft declared that dispensing controlled substances pursuant to the Dignity Act would furnish a basis for a revocation or suspension proceeding pursuant to 21 U.S.C. § 824(a)(4). Pets. App. at 102a. This means that Ashcroft pre-determined that, solely on the basis of such conduct's purported inconsistency with federal law, he could revoke or suspend a practitioner's registration pursuant to § 824(a)(4)—a result at odds with § 823(f), which requires consideration of all five factors therein. Unless the Attorney General is willing to rescind this aspect of the Directive, it must comply with § 823(f).

Petitioners also argue that affirmance of the Court of Appeals' ruling would violate the CSA "by requiring the Attorney General to make one factor—compliance with state law—determinative of" whether a physician's registration is consistent with the public interest. Pets. Br. at 49-50. This is a straw man. Enjoining enforcement of the Directive would not render compliance with state law exclusively determinative; rather, it would simply preclude revocation or suspension based solely on a physician's having prescribed controlled substances in accordance with state law to facilitate physician-assisted dying.

the state in which he or she is licensed in dispensing controlled substances for physician-assisted dying. The second and third factors are not necessarily implicated by participation in physician-assisted dying. The fourth factor is satisfied with respect to state and local laws provided that the physician complies with them. Ashcroft thus expressly dismissed the first and fourth factors' references to state law when he determined that the Directive's "conclusion applies regardless of whether state law authorizes or permits" physician-assisted dying. Pets. App. at 102a. As for the federal law element of the fourth factor, Respondents' briefs elsewhere make plain that federal law does not authorize the Attorney General to prohibit physician-assisted dying. As for the fifth factor, the Oregon data make clear that prescribing controlled substances in accordance with responsible state laws like the Dignity Act does not threaten the public health and safety. For these reasons and others, Ashcroft violated the CSA when he ruled that dispensing controlled substances in connection with physician-assisted dying, even when consistent with state law, is by itself a sufficient basis for revocation or suspension of a practitioner's license under 21 U.S.C. § 824(a)(4).

III. In Grappling with the Issue of Assisted Dying, Oregon Is Fulfilling its Intended Role as a Laboratory of Social Experimentation.

Justice O'Connor provided the critical fifth vote in *Glucksberg*, and supported it with a call for the issue of physician-assisted dying to be "entrusted to the laboratory of the states." *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring) (quoting *Cruzan*, 497 U.S. at 292) (quotes omitted). The idea of the "laboratory of the states" as engines of social experimentation has a deeply rooted history in the fabric of constitutional doctrine. Justice Brandeis first brought the analogy to life over seventy years ago, emphasizing the power of the states to amend their practices and institutions to meet changing social and economic needs. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (one of the "happy incidents" of federalism is that "a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country"; denial of the "right to experiment" may create "serious consequences for the nation"); *id.* at 280 (it is not necessary to challenge the authority of the states to indulge in experimental legislation as long as they adhere to limitations imposed by the Federal Constitution).

Since Justice Brandeis's *New State Ice Co.* opinion, this Court's opinions have repeatedly emphasized the benefits of social experimentation by the states.[53] Members of this Court have frequently relied on the principles articulated

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[53] *See, e.g., United States v. Lopez*, 514 U.S. 549, 575 (1995) (Kennedy, J., concurring) (When "considerable disagreement" exists about how best to accomplish a desired goal, "the theory and utility of our federalism are revealed, for the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear"); *Arizona v. Evans*, 514 U.S. 1, 26 (1995) (Ginsburg, J., dissenting) (to encourage experimentation and promote solution of empirical questions, Court should encourage state exploration of different modes of protecting individual rights); *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 546 (1985), *overruled on other grounds* ("The science of government * * * is the science of experiment"); *EEOC v. Wyoming*, 460 U.S. 226, 265 (1983) (Burger, C.J., dissenting), *overruled on other grounds* ("Flexibility for experimentation not only permits each state to find the best solutions to its own problems, it is the means by which each state may profit from the experiences and activities of all the rest."); *Santosky v. Kramer*, 455 U.S. 745, 771 (1982) (Rehnquist, C.J., dissenting) (leaving the States

by Justice Brandeis to analyze some of the most profound and relevant social issues of the day.[54]

Indeed, several Justices in addition to Justice O'Connor invoked the doctrine when this Court addressed similar confluxes of medical policy and individual liberty at the end of life in *Cruzan* and *Glucksberg*. In the first of these, Justice Scalia stated the issue succinctly: "The States have begun to grapple with" the "difficult, indeed agonizing, questions that are presented by the constantly increasing power of science to keep the human body alive for longer than any reasonable person would want to inhabit it."

free to experiment with various remedies to a difficult social problem produces novel approaches and promising progress."); *San Antonio Independent School Dist. v. Rodriguez*, 411 U.S. 1, 50 (1973) (experimentation allows social policy to benefit from a "multiplicity of viewpoints and from a diversity of approaches").

[54] *See, e.g., Raich*, 125 S. Ct at 2220 (O'Connor, J., dissenting) ('medical marijuana' statute should not be restricted, in part because Court should protect states' role as laboratories); *Oakland Cannabis Buyers' Cooperative*, 532 U.S. at 502 (Stevens, J., concurring) ('medical marijuana' statute should be upheld; Court should minimize legal conflict between the federal and state governments when state's citizens have chosen to serve as a laboratory without risk to the rest of the country); *Atkins v. Virginia*, 536 U.S. 304, 326 (2002) (Rehnquist, C.J., dissenting) (Court should uphold state statute permitting execution of mentally retarded, which is developed "through the workings of normal democratic processes in the laboratories of the States"); *Boy Scouts of America v. Dale*, 530 U.S. 640, 664 (2000) (Stevens, J., dissenting) (state anti-discrimination statute should be upheld as permissible and necessary social experimentation); *Zelman v. Simmons-Harris*, 536 U.S. 639, 680 (2002) (Thomas, J., concurring) (state funding to religious schools is proper; Fourteenth Amendment should not "handcuff the State's ability to experiment with education"); *id.* at 685 (Stevens, J., dissenting) (Court should not accept state funding of religious education before permitting recent state experimentation with alternative public schools to take effect).

Cruzan, 497 U.S. at 292 (Scalia, J., concurring). Similarly, Justice Souter wrote in *Glucksberg* that, "Legislatures, on the other hand, have superior opportunities to obtain the facts necessary for a judgment about the present controversy * * *. [T]heir mechanisms include the power to experiment, moving forward and pulling back as facts emerge within their own jurisdictions." 521 U.S. at 788 (Souter, J., concurring). The *Glucksberg* majority implicitly endorsed experimentation in the context of physician-assisted dying when it acknowledged that Oregon's policy was not arrived at on a whim but rather was the result of serious democratic debate. *See id.* at 719 (describing various state policies, including Oregon's, on physician-assisted dying and concluding that "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues"). Indeed, the Court recognized the "earnest and profound debate" occurring across the nation on the issue of physician-assisted dying, and concluded with the declaration that "[o]ur holding permits this debate to continue, as it should in a democratic society." *Id.* at 736.

Oregon's experience with physician-assisted dying illustrates the concrete benefits of state-based experimentation with the profound issues of death and autonomy and confirms the wisdom of promoting the states' role as engines of social change. One of the most important benefits arising from Oregon's experience is the generation of scientifically validated, objective empirical data regarding physician-assisted dying—information that was lacking in the debate prior to the Dignity Act's enactment.[55] The annual reports

[55] *Cf. Globe Newspaper Co. v. Superior Court for Norfolk County* 457 U.S. 596, 617 (1982) ("It makes no sense to criticize the [State] for its failure to offer empirical data in support of its rule; only by

generated pursuant to the Dignity Act have provided other states confronting the issues of end of life care with immense insights into physician-assisted dying. For example, Vermont is currently considering a bill very similar to Oregon's Death with Dignity Act.[56] When last it considered such a bill,[57] it commissioned a study examining end of life issues that drew heavily on Oregon's experience.[58] California is presently considering the issue as well.[59] The legislatures of both Hawaii[60] and Arizona also recently considered the enactment of similar statutes.

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allowing state experimentation may such empirical evidence be produced."). As noted above, *see* n.44, *supra*, these data were not available to this Court when last it addressed this issue in *Glucksberg*.

[56] *See* H.R. 168, 2005 Leg., 2005-06 Sess. (Vt. 2005); text *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/bills/intro/H-168.HTM.

[57] *See* H.R. 318, 2003 Leg., 2003-04 Sess. (Vt. 2004), *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2004/bills/intro/H-318.HTM

[58] *See* R. Lunge *et al.*, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes* (2004) (survey requested by Vermont legislators), *available at* http://www.leg.state.vt.us/reports/04Death/Death_With_Dignity_Report.htm. This study concluded that "it is apparent from credible sources in and out of Oregon that the Death with Dignity Act has not had an adverse impact on end-of-life care and in all probability has enhanced the other options." *Id.* at 30.

[59] *See* A.B. 654, 2005 Sess. (Cal. 2005), *available at* http://www.aroundthecapitol.com/billtrack/billview.html?bill=AB_654. For a description of the legislation, see http://democrats.assembly.ca.gov/members/a01/articles/an012005016.htm

[60] During Hawaii's 2002 legislative session, a bill modeled on Oregon's Death With Dignity Act passed through the house and came within two votes of passage in the Senate. This bill was reintroduced in 2004 and likely will be reintroduced again.

The advances in understanding and awareness that have resulted from Oregon's earnest and informed debates are not an accident, but rather exactly the sort of wisdom that our federal system was designed to foster. Since *Glucksberg* was decided, Oregon's experience with physician-assisted dying has provided the nation with its only source of scientific and objective data on the practice of physician-assisted dying and social attitudes towards it. Such data amply demonstrate the benefits of Oregon's experiment with dignified dying, and the wisdom of leaving the responsibility for its outcome with its citizens. Oregon's experience with the Dignity Act has proven beneficial to Oregonians, and its social experiment has proven beneficial to the nation as a whole. It is precisely these kinds of benefits that this Court's jurisprudence is intended to foster.

As noted above and explained in greater detail in the briefs of the other Respondents, the CSA does not interfere with the "historic primacy of state regulation of matters of health and safety."[61] Thus, both the intent of Congress as evidenced by the plain language of the CSA and this Court's approach to the profound issues of health policy and individual liberty that underlie this case require that the Directive be enjoined as an act of overstepping by the U.S. Attorney General.

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[61] *Medtronic, Inc*, 518 U.S. at 485; *see also* n.11, *supra*.

CONCLUSION

For the foregoing reasons, the Patient-Respondents respectfully submit that the judgment by the Court of Appeals should be affirmed.

Respectfully submitted,

/s/ NICHOLAS W. van AELSTYN

NICHOLAS W. van AELSTYN
Counsel of Record
AARON S. JACOBS
DAVID A. THOMAS
HELLER EHRMAN LLP
333 Bush Street
San Francisco, CA 94104-2878
Telephone: (415) 772-6000
Facsimile: (415) 772-6268

Counsel for Patient-Respondents

KATHRYN L. TUCKER
COMPASSION & CHOICES
1201 3rd Avenue, 40th Floor
Seattle, WA 98101-3000
Telephone: (206) 367-2134
Facsimile: (206) 583-8500

Counsel for Patient-Respondents

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31

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In The Supreme Court of the United States

ALBERTO R. GONZALES,
ATTORNEY GENERAL, et al.,

Petitioners,

v.

STATE OF OREGON, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE STATES OF CALIFORNIA, MISSISSIPPI, MISSOURI, MONTANA, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF RESPONDENT STATE OF OREGON

BILL LOCKYER
Attorney General of the
State of California

TAYLOR S. CAREY*
Special Assistant Attorney General
1300 I Street
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-7562
Fax: (916) 322-0206
Counsel for Amici Curiae
**Counsel of Record*

[Additional Counsel Listed On Inside Cover]

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

JIM HOOD
Attorney General
State of Mississippi
Post Office Box 220
Jackson, MS 39205
(601) 359-3820

JEREMIAH W. (JAY) NIXON
Attorney General
State of Missouri
Supreme Court Building
207 West High Street
Jefferson City, MO 65101
(573) 751-3321

MIKE MCGRATH
Attorney General
State of Montana
P.O. Box 201401
Helena, MT 59620-1401
(406) 444-2026

ROBERT J. SPAGNOLETTI
Attorney General
District of Columbia
John A. Wilson Building
1350 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 727-3400

TABLE OF CONTENTS

	Page
INTEREST OF AMICI CURIAE	1
SUMMARY OF ARGUMENT	2
ARGUMENT	3
ADMINISTRATIVE INTERFERENCE WITH STATE AUTHORIZATION OF A MEDICAL PROCEDURE MUST BE GROUNDED IN CONGRESS' CLEARLY EXPRESSED INTENT TO SUPERVISE STATE REGULATION OF MEDICAL PRACTICE; NO SUCH EXPRESSION IS EVIDENT IN THE CSA	3
A. Regulation of Medical Practice, Including End-of-life Issues, Is Traditionally Left to the Sovereign and Independent Policy Judgment of Each State	3
B. Congress Did Not Intend in the Controlled Substances Act to Delegate to the Attorney General Authority to Supervise State Regulation of Medical Practice	11
CONCLUSION	16

TABLE OF AUTHORITIES – Continued

Page

CASES

Addington v. Texas, 441 U.S. 418 (1979) 3

Alaska Department of Environmental Conservation v. Environmental Protection Agency, 540 U.S. 461, 124 S.Ct. 983 (2004) 12

Anderson v. Dunn, 19 U.S. (6 Wheat.) 204 (1821) 8

Barsky v. Board of Regents of the State University of New York, 347 U.S. 442 (1954) 2, 4

Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001) 14

Canterbury v. Spence, 464 F.2d 772 (C.A.D.C. 1972) 9

Christensen v. Thornby, 255 N.W. 620 (Minn. 1934) 6

Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990) 10

DeBuono v. NYSA-ILA Medical and Clinical Services Fund, 520 U.S. 806 (1997) 12

Eastlake v. Forest City Enterprises, Inc., 526 U.S. 668 (1966) 3

F.E.R.C. v. Mississippi, 456 U.S. 742 (1982) 9

Franchise Tax Bd. of California v. Hyatt, 538 U.S. 488 (2003) 2, 9

G.B. v. Lackner, 145 Cal.Rptr. 555 (Cal. App. 1978) 7

Garcia v. San Antonio Metropolitan Transit Authority, 469 U.S. 528 (1985) 10

Gonzalez v. Raich, 545 U.S. ___, 125 S.Ct. 2195 (2005) 5, 12, 13

Gregory v. Ashcroft, 501 U.S. 452 (1991) 11

TABLE OF AUTHORITIES – Continued

Page

Griswold v. Connecticut, O.T. 1964, No. 496, p. 75 5

Hillsborough County Florida v. Automated Medical Laboratories, Inc. 471 U.S. 707 (1985) 12

Jessin v. Shasta County, 79 Cal.Rptr. 359 (Cal. App. 1969) 6

Linder v. United States, 268 U.S. 5 (1924) 1, 4

Medtronic Inc. v. Lohr, 518 U.S. 470 (1996) 4, 11

Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985) 4

Mistretta v. United States, 488 U.S. 361, 109 S.Ct. 647 (1989) 13

New State Ice Co. v. Liebmann, 285 U.S. 262 (1932) 3, 8

Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992) 4, 10

Poe v. Ullman, 367 U.S. 497 (1961) 10

Reeves v. Stake, 447 U.S. 429 (1980) 10

Roe v. Wade, 410 U.S. 113 (1973) 5, 6

Rush v. Johnson, 565 F.Supp. 856 (D.C. Ga. 1983) 7

Solid Waste Agency of Northern Cook County v. United States Corps of Engineers, 531 U.S. 159 (2001) 2, 11, 12

United States v. Moore, 423 U.S. 122 (1975) 13

Washington v. Glucksburg, 521 U.S. 702 (1997) 9

TABLE OF AUTHORITIES – Continued

Page

STATUTES AND REGULATIONS

21 U.S.C. § 301 *et seq.* 14

21 U.S.C. § 801 *et seq.* ..... *passim*

21 U.S.C. § 903 14

28 U.S.C. § 823(a)(4) 14

28 U.S.C. § 823(f) 14

21 C.F.R. 1306.04 11

22A Am. Jur.2d Dead Bodies § 3 (1988) 8

Cal. Health & Saf. Code, §§ 24185, 125300 (2005) 5

Cal. Pen. Code § 401 (2005) 1

Conn. Gen. Stat. Rev. § 53-33 (1958) 7

Miss. Code Ann. § 97-3-49 1

Mo. Rev. Stat. § 565.023 (2000) 1

Mont. Code Ann. § 45-5-105 (2003) 1

N.J. Stat. Ann. § 26:2Z-2 (West Supp. 2004) 5

Or. Rev. Stat. §§ 127.800-127.995 (2003) 4

Pub.L. No. 75-717, 52 Stat. 1040 (1938) 14

OTHER AUTHORITIES

4 William Blackstone, Commentaries 6, 8

15 Ops. Cal. Atty. Gen. 100 (1950) 6

TABLE OF AUTHORITIES – Continued

Page

Andrews, *Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cell Research, Therapeutic Cloning and Reproductive Cloning*, Appendix E to *Monitoring Stem Cell Research*, President's Council on Bioethics (January 2004) 5

Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71 (1998) 14

Beh & Diamond, *An Emerging Ethical and Medical Dilemma: Should Physicians Perform Sex Assignment Surgery on Infants With Ambiguous Genitalia?*, 7 Mich. J. Gender & L. 1 (2000) 7

Bridy, *Confounding Extremities: Surgery at the Medico-Ethical Limits of Self-Modification*, 32 J.L. Med. & Ethics 148 (2004) 7

Campbell & Glass, *The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research*, 46 McGill L. J. 473 (2001) 9

Cate, *Human Organ Transplantation: The Role of Law*, 20 J. Corp. L. 69 (1995) 8

Champlin & Winslow, *Elective Sterilization*, U. Pa. L. Rev. 415 (1965) 7

Graber, *The Ghost of Abortion Past: Pre-Roe Abortion Law in Action*, 1 Va. J. Soc. Pol'y & L. 309 (1994) 5

Hong, *Categorical Exclusions: Exploring Legal Responses to Health Care Discrimination Against Transsexuals*, 11 Colum. J. Gender & L. 88 (2002) 6

H.R. 4006, 105th Cong. (1998) 15

TABLE OF AUTHORITIES – Continued

Page

Keller, *The Bed of Life: a Discussion of Organ Donation, Its Legal And Scientific History, And a Recommended "Opt-out" Solution to Organ Scarcity*, 32 Stetson L. Rev. 855 (Summer 2003) 8

Miller & Dean, *Liability of Physicians for Sterilization Operations*, XVI ABA Journal 158 (1930) 6

Tribe, *American Constitutional Law* (3d ed.) 10

Twardy, *Medicolegal Aspects of Transsexualism*, 26 Medical Trial Technique Q. 249 (Winter 1980) 6

INTEREST OF AMICI CURIAE

Amici States all regulate the practice of medicine. They are all concerned about the need to balance respect for personal liberty and the interests of their broader societies in addressing sensitive end-of-life issues. Amici states all prohibit physician assisted suicide.[1] Nevertheless, amici support the State of Oregon in this matter because petitioners claim administrative authority to interfere with Oregon's regulation of the practice of medicine. Such a claim must be supported by unmistakable congressional authorization. It is not.

At issue here, is not the question of Congress' authority to regulate the practice of medicine. Rather, the question is whether Congress intended in the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, to regulate the practice of medicine. That is, did Congress intend to delegate to the United States Attorney General authority to supervise state regulation of the practice of medicine by prosecuting duly licensed physicians and denying them the ability to practice their trade – for *lawfully* prescribing Schedule II drugs in medical procedures that the Attorney General deems to be "illegitimate."

Regulation of the practice of medicine has long been regarded as the responsibility of the individual sovereign States. See, *e.g, Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the states is beyond the power of the federal government."). Amici, therefore, join Oregon in contending that the United States Attorney General's assertion of the prerogative to evaluate a State's legislative policy concerning

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[1] See, *e.g.*, Cal. Pen. Code § 401 (2005); Mo. Rev. Stat. § 565.023 (2000); Mont. Code Ann. § 45-5-105 (2003); Miss. Code Ann. § 97-3-49.

medical practice and the physician-patient relationship must be grounded in "a clear indication that Congress intended that result." *Solid Waste Agency of Northern Cook County v. United States Corps of Engineers*, 531 U.S. 159, 172 (2001). Amici further contend that such a sweeping grant of federal power is not included in the Controlled Substances Act.

SUMMARY OF ARGUMENT

Physicians have long understood that prescribing Schedule II narcotics in violation of state law may subject them to federal prosecution and loss of prescribing privileges under the Controlled Substances Act. But, for the first time in the 30-year history of that Act, duly licensed physicians in Oregon face federal prosecution and administrative penalties because they prescribed a Schedule II narcotic *in full compliance* with state law. The sole offense of these doctors will be participation in a medical procedure that, though sanctioned under Oregon state law, is not similarly sanctioned by other States or by professional organizations and is, therefore, deemed to be "illegitimate" by the Attorney General of the United States.

This is a dramatic alteration of the traditional federal-state allocation of legislative responsibility. States have generally enjoyed "broad powers" in matters concerning the practice of medicine for protection of the health and welfare of their citizens. *Barsky v. Board of Regents of the State University of New York,* 347 U.S. 442, 449 (1954). And a value consensus among the States regarding medical matters is not a measure of the validity of any one State's legislative policy Cf., *Franchise Tax Bd. of California v. Hyatt*, 538 U.S. 488 (2003) (Full Faith and Credit

Clause does not compel a State to substitute statutes of other States for its own statutes dealing with a subject matter concerning which it is competent to legislate). Indeed, experimentation by States in the regulation of social matters has long been regarded as a bedrock of Federalism. See *New State Ice Co. v. Liebmann,* 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (States as "laboratories" of democracy.) "The essence of federalism is that states must be free to develop a variety of solutions to problems and not be forced into a common, uniform mold." *Addington v. Texas*, 441 U.S. 418, 431 (1979).

An intrusion into the traditional purview of state legislative control by an administrative agency such as is effected by the Attorney General's "directive" here must be grounded in a clear expression of congressional intent. However, nothing in the Controlled Substances Act delegates to the Attorney General authority to interfere with State regulation of the practice of medicine.

ARGUMENT

ADMINISTRATIVE INTERFERENCE WITH STATE AUTHORIZATION OF A MEDICAL PROCEDURE MUST BE GROUNDED IN CONGRESS' CLEARLY EXPRESSED INTENT TO SUPERVISE STATE REGULATION OF MEDICAL PRACTICE; NO SUCH EXPRESSION IS EVIDENT IN THE CSA.

A. Regulation of Medical Practice, Including End-of-life Issues, Is Traditionally Left to the Sovereign and Independent Policy Judgment of Each State.

In November 1994, by ballot initiative, a "basic instrument of democratic government," *Eastlake v. Forest*

City Enterprises, Inc., 526 U.S. 668, 679 (1966), Oregon voters enacted the Death With Dignity Act, Or. Rev. Stat. §§ 127.800-127.995 (2003). The citizens of Oregon subsequently reaffirmed the measure when, in November 1997, an initiative seeking its repeal was defeated.

Traditionally, States "have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Medtronic Inc. v. Lohr*, 518 U.S. 470, 475 (1996), quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). This Court has characterized as "elemental" the proposition that States have "broad power" to establish within their borders standards of conduct relative to health. *Barsky v. Board of Regents of the State University of New York*, 347 U.S. at 449; see also, *Linder v. United States*, 268 U.S. at 18.

The scope of the States' inherent authority over medical practice cannot be confined to ascertaining whether accepted medical procedures have been competently performed. It reasonably must include the authority to decide what medical procedures are acceptable to perform in the first instance and, within the Constitution's limits, to specify the conditions under which medical procedures may be lawfully performed. Cf., *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992) (confirming State's interest in regulating abortion availability after viability).

Seldom have States been of one mind, as a matter of legislative policy, about the "legitimacy" of every new medical procedure that develops. Most recently, the Court

noted state variation in authorizing the use of marijuana in medical treatment. *Gonzalez v. Raich*, 545 U.S. ___, 125 S.Ct. 2195, 2198-99 (2005) (noting that at least ten States authorize marijuana for medical purposes). And today, States wrestle with difficult ethical issues surrounding human stem cell research. Eight States, for example, have enacted explicit laws to ban reproductive cloning; four of those also ban therapeutic cloning; and one State only prohibits the use of state funding in reproductive cloning Andrews, *Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cell Research, Therapeutic Cloning and Reproductive Cloning*, Appendix E to *Monitoring Stem Cell Research*, President's Council on Bioethics (January 2004).[2] Some of the States that ban reproductive cloning actively encourage therapeutic cloning.[3]

State policy disagreement over some medical procedures has been a reality for much of our history. Birth control and abortion are obvious examples of medical procedures that some States came to accept as a matter of state policy while others did not. At the time of this Court's decision in *Griswold v. Connecticut*, 381 U.S. 479 (1965), for example, 30 States had laws relating to birth control. See Brief for Appellee in *Griswold v. Connecticut*, O.T. 1964, No. 496, p. 7. In 1960, thirteen years before *Roe v. Wade*, 410 U.S. 113 (1973), every state criminal code included provisions forbidding abortion under most circumstances. Graber, *The Ghost of Abortion Past: Pre-Roe Abortion Law in Action*, 1 Va. J. Soc. Pol'y & L. 309, 360

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[2] Available at: http://www.bioethics.gov/reports/stemcell/appendix_e.html.

[3] See, *e.g.*, Cal. Health & Saf. Code, §§ 24185, 125300 (2005); N.J. Stat. Ann. § 26:2Z-2 (West Supp. 2004).

(1994). But by 1973, some state legislatures had removed those restrictions,[4] while in other States therapeutic abortion remained a proscribed medical procedure as a matter of local legislative choice.

Sex-reassignment surgery is another example of a medical procedure whose "legitimacy" may be questioned by some but which is nevertheless permitted in States today. According to one commentator, "[t]he national and international medical community overwhelmingly endorses sex-reassignment surgery and hormones as the only known medical treatment for transsexuals." Hong, *Categorical Exclusions: Exploring Legal Responses to Health Care Discrimination Against Transsexuals*, 11 Colum. J. Gender & L. 88, 91 & n. 18 (2002). But at common law, castration amounted to felonious mayhem, 4 William Blackstone, Commentaries *206, and consent to mayhem was no defense, see Twardy, *Medicolegal Aspects of Transsexualism*, 26 Medical Trial Technique Q. 249, 297-310 (Winter 1980). Indeed, in the opinion of some, the common law criminalization of castration precluded even voluntary vasectomy. See, *e.g.*, 15 Ops. Cal. Atty. Gen. 100, 103 (1950), *citing* Miller & Dean, *Liability of Physicians for Sterilization Operations,* XVI ABA Journal 158, 159 (1930); but see *Jessin v. Shasta County*, 79 Cal.Rptr. 359 (Cal. App. 1969); *Christensen v. Thornby,* 255 N.W. 620, 622 (Minn. 1934) ("[A vasectomy] does not render the patient impotent or unable 'to fight for the king,' as was

[4] Prior to *Roe*, statutes permitting non-therapeutic abortions had been enacted in Hawaii (1971), New York (1971), Alaska (1970) and Washington (1971). *Id.*

the case in mayhem or maiming").[5] Today, no state expressly prohibits male-female sex-reassignment surgery, though States are not always in agreement about the therapeutic value of the medical procedure. Compare, *e.g.*, *Rush v. Johnson*, 565 F.Supp. 856 (D.C. Ga. 1983); (State's determinations that "transsexual" surgery was not generally accepted by the professional medical community as a proven and effective treatment and that there was no authority of evidence that the surgery is safe and effective were reasonable) and *G.B. v. Lackner*, 145 Cal.Rptr. 555 (Cal. App. 1978) (proposed surgery to reconstruct genitalia as treatment for gender identity dysphoria could not be arbitrarily classified as "cosmetic" and thus claimant was entitled to Medi-Cal assistance).[6]

The extremely important medical procedure of organ transplantation could never have developed were it not for

[5] One comment reports that as of 1965, three States had enacted statutes declaring voluntary sterilization (male or female) to be a crime "unless performed under the provisions of the compulsory eugenic statutes or by a private physician where there is a 'medical necessity'" Champlin & Winslow, *Elective Sterilization*, U. Pa. L. Rev. 415, 427 (1965). And one of those statutes imposed criminal penalties on the person submitting to the procedure. *Id.*; Conn. Gen. Stat. Rev. § 53-33 (1958).

[6] Still today, States must wrestle with the legal/ethical question whether sex-change operations may be performed *involuntarily* on intersexed children who are too young to consent. See, *e.g.*, Beh & Diamond, *An Emerging Ethical and Medical Dilemma: Should Physicians Perform Sex Assignment Surgery on Infants With Ambiguous Genitalia?*, 7 Mich. J. Gender & L. 1 (2000). And, as the complexity of the human condition is slowly being recognized, States will be called upon to consider the ethical and legal parameters appropriate to medical disfigurement procedures at what are certainly the "outer edges" of today's acceptability. See, *e.g.*, Bridy, *Confounding Extremities: Surgery at the Medico-Ethical Limits of Self-Modification*, 32 J.L. Med. & Ethics 148 (2004).

the willingness of States to depart from common law proscriptions in deference to changes in public sentiment. At common law, no one had power to convey his body parts after death, because the common law recognized no property right in one's body See 22A Am. Jur. 2d Dead Bodies, § 3 (1988). And anatomical dissection at common law was so reprehensible a notion as to have been reserved as an additional post-mortem punishment to exact against the corpse of an executed murderer. See 4 William Blackstone, Commentaries *202; Keller, *The Bed of Life: a Discussion of Organ Donation, Its Legal And Scientific History, And a Recommended "Opt-out" Solution to Organ Scarcity*, 32 Stetson L. Rev. 855, 863-64 (Summer 2003). States initially differed on their treatment of body and organ donation, but in the 1960s, the National Conference of Commissioners on Uniform State Laws began the process of formulating a model organ donation act. By 1972, some version of the Uniform Anatomical Gift Act had been adopted in every State and the District of Columbia. See Cate, *Human Organ Transplantation: The Role of Law*, 20 J. Corp. L. 69, 71 & n. 24 (1995).

Advances in medicine and advances in understanding of the human physical and psychological condition increasingly present issues of great sensitivity and controversy. But, "[t]he science of government ... is the science of experiment," *Anderson v. Dunn*, 19 U.S. (6 Wheat.) 204, 226 (1821), and the Court has often acknowledged the States' important role as "laboratories" of democracy. *New State Ice Co. v. Liebmann* 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of

the country.") The Constitution does not compel policy consensus among the States. Cf. *Franchise Tax Bd. of California v. Hyatt*, 538 U.S. 488 (2003) (Full Faith and Credit Clause does not compel a State to substitute statutes of other States for its own statutes dealing with a subject matter concerning which it is competent to legislate).[7]

State experimentation in social policy has been the source of many important innovations, such as the right of women to vote, the advent of unemployment insurance and minimum-wage laws, and environmental protection. See *F.E.R.C. v. Mississippi*, 456 U.S. 742, 788-89 (1982) (O'Connor, J., dissenting). The Court recognized nearly a decade ago that the States were "engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Washington v. Glucksburg*, 521 U.S. 702, 719 (1997). Indeed, the Court was concerned that, by extending constitutional protection to an asserted right to end one's life, it would, "to a great extent, place the matter outside the arena of public debate and legislative action." *Id.* at 720.

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[7] Nor have the States surrendered their policy-making responsibility to professional associations. At best, the views and opinions of professional associations amount to a kind of "soft law," Campbell & Glass, *The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research*, 46 McGill L. J. 473 (2001), guiding the conduct of members but having no constitutional status elevating those views over the legislative choices of the States within which the members practice. Indeed, state legislatures may determine that public necessity and circumstance warrant a quality of medical practice different from that which is currently accepted within the profession. As one court observed, "[r]espect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves." *Canterbury v. Spence*, 464 F.2d 772, 784 (C.A.D.C. 1972) (re sufficiency of surgeon's disclosure).

Federalism's wisdom of deferring to the States' inventiveness for solving pressing issues of public health and welfare has no less force because one State's experiment challenges conventional norms. Reflection on the traditions from which States *break* is as important as reflection on the traditions to which they *adhere* in discerning an appropriate constitutional balance between respect for individual rights and the demands of organized society. See *Poe v. Ullman*, 367 U.S. 497, 542 (1961) (Harlan, J., dissenting from dismissal on jurisdictional grounds), quoted in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 849 (1992); cf., *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 545-46 (1985) (The "essence of our federal system is that within the realm of authority left open to them under the Constitution, the States must be equally free to engage in any activity that their citizens choose for the common weal, no matter how unorthodox or unnecessary anyone else . . . deems state involvement to be."). If "federalism's capacity for institutional innovation," Tribe, *American Constitutional Law* (3d ed.) 910, justifies deference to state experimentation with remedies for chronic cement shortages, see *Reeves v. Stake*, 447 U.S. 429, 441 (1980), it surely justifies deference to state experimentation in resolution of "the difficult, indeed agonizing, questions that are presented by the constantly increasing power of science to keep the human body alive for longer than any reasonable person would want to inhabit it." *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 292 (1990) (Scalia, J., concurring).

B. Congress Did Not Intend in the Controlled Substances Act to Delegate to the Attorney General Authority to Supervise State Regulation of Medical Practice.

This case does not present the question whether Congress could, under the Commerce Clause, preempt the States in regulating physician treatment of end-of-life matters, though the presumption would certainly be against such preemption. *Medtronic, Inc.*, 518 U.S. at 485. In any event, petitioners here do not squarely argue that Congress intended in the CSA to preempt state regulation of end-of-life medical decisions.

Rather, petitioners rely on the phrase "legitimate medical purpose," which appears in an administrative regulation implementing the CSA, 21 C.F.R. 1306.04. Certainly, that phrase gives the Attorney General power to evaluate the veracity of a physician's asserted justification for prescribing a Schedule II drug. But petitioners argue that the phrase must also be understood to authorize the Attorney General to evaluate the merits of a State's legislative policy in authorizing the prescription under state law in the first instance.

Inasmuch as petitioners claim delegation of the power to preemptively interfere with Oregon's choice to authorize Oregon physicians to perform a medical procedure exclusively within that State, petitioners "invoke the outer limits of Congress' power" and must, therefore, demonstrate "a clear indication that Congress intended that result." *Solid Waste Agency of Northern Cook County v. United States Corps of Engineers*, 531 U.S. 159, 172 (2001); see also *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) ("[I]f Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its

intention to do so unmistakably clear in the language of the statute"); *Alaska Department of Environmental Conservation v. Environmental Protection Agency*, 540 U.S. 461, 513 (2004) (Kennedy, J., concurring) ("[i]f, by some course of reasoning, state[s] . . . must live with the insult that their judgments can be revised by a federal agency, the Court should at least insist upon a clear instruction from Congress.")[8] Whether Congress has the power to impose on a State its view of the "legitimacy" of a medical procedure is not presented here.[9] Rather, the question here

[8] Petitioners dismiss *Solid Waste Agency* as irrelevant. Br. for Pet. at 41 n. 16. But petitioners would have the Court read *Solid Waste Agency* at such a high level of abstraction as to render it meaningless to limit exercise of administrative authority. In this case, the United States Attorney General does not merely invoke congressional power to regulate the distribution of controlled substances as a matter of interstate commerce. Rather, the Attorney General invokes an asserted congressional power to determine – *for the States* – the "legitimacy" as a medical procedure of a use to which a Schedule II drug may lawfully be put under state law. Such a power, touching as it does on an area of traditional state governance, is indeed at the "outer limits" of congressional authority. Cf., *Hillsborough County Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985) (presumption against an intent by Congress in the FDA to preempt local regulation for the protection of blood plasma donors); see also, *DeBuono v. NYSA-ILA Medical and Clinical Services Fund*, 520 U.S. 806, 807 (1997) (no ERISA preemption of state health facility assessment because the assessment "clearly operates in a field that has been traditionally occupied by the States: the regulation of health and safety matters.").

[9] This Court has not yet squarely addressed the question of Congress' power to preempt a State's legislative determination that marijuana has a legitimate medical purpose. See *Gonzalez v. Raich*, 125 S.Ct. at 2204-05 (2005) ("[R]espondents' challenge is actually quite limited; they argue that the CSA's categorical prohibition of the manufacture and possession of marijuana as applied to the intrastate manufacture and possession of marijuana for medical purposes pursuant to California law exceeds Congress' authority under the Commerce Clause."); see also *id.* at 2231 n. 3 (Thomas, J., dissenting); *Raich* held only that, *given* Congress' determination that marijuana has

(Continued on following page)

is whether in the CSA can be found a delegation to the Attorney General of authority preemptively to interfere with a State's administration of its medical practice laws, based on an evaluation of the authorized practice's "legitimacy" – especially when "legitimacy" is not measured against a constitutional standard, but by the approbation of other States and professional medical organizations.

The "main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzalez v. Raich*, 545 U.S. ___ (2005). The CSA was "designed to deal in comprehensive fashion with the growing menace of drug abuse in the United States[.]" *United States v. Moore*, 423 U.S. 122, 141 (1975).

This is not to suggest, of course, that the Attorney General lacks rule making authority under the CSA. But the Attorney General's use of his rule making authority in this instance expands the role of his office into a sort of "junior-varsity Congress," *Mistretta v. United States* 488 U.S. 361, 472, 109 S.Ct. 647, 683 (1989) (Scalia, J., dissenting), substituting a federal agency's notions of medical propriety for the informal legislative policy of the States.

no accepted medical use in treatment – a proposition with which the States were presumably in agreement at the time of enactment – Congress may lawfully proscribe even wholly intrastate cultivation and use of marijuana, notwithstanding that the cultivation and use may be lawful under state law.

Certainly, the legislative history of the CSA suggests a congressional intent to regulate the abuse of prescription privileges to furnish Schedule II drugs in a manner *inconsistent* with accepted medical practice in a State. See 28 U.S.C. §§ 823(f) & 823(a)(4). But nothing in the legislative history of the Act suggests Congress' intention to correct State authorization of permissible uses of Schedule II narcotics.

This "hands-off" policy in respect to regulation of the practice of medicine is consistent with the historic understanding of Congress' intent under the Food, Drug and Cosmetic Act, Pub.L. No. 75-717, 52 Stat. 1040 (1938), codified as amended 21 U.S.C. § 301 *et seq.* (1994). Under long-standing practice, physicians may use legally marketed drugs in any way that they believe, in their professional judgment, will best serve their patients – a prerogative that is repeatedly recognized by the courts and the FDA itself. See Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,* 53 Food & Drug L.J. 71, 76-77 (1998), cited in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001). Moreover, several state statutes recognize off-label uses in varying contexts. Beck & Azari, *supra*, at 76 n. 56. Nothing in the CSA suggests Congress' intent to change this paradigm of deferring to state regulation of professional prescription practices. Indeed, Congress expressly stated its intention not to preempt state laws that are otherwise within the authority of a State to enact. 21 U.S.C. § 903.

It is evident that former Attorney General Janet Reno saw nothing in the Act or its legislative history to persuade her in 1998 of Congress' intent to enter this area. To the contrary, she noted in a letter to the Chairman of the

House Judiciary Committee that the CSA was not "intended to displace the states as the primary regulators of the medical profession or to override a state's determination as to what constitutes legitimate medical practice." See Pet. App. 7a. The CSA has not been amended since 1998 to suggest that Attorney General Reno was wrong.[10]

Certainly, Congress can state legislative policies under its Commerce Clause powers. And Congress has nullified state legislative choices in furtherance of its powers under the Fourteenth and Fifteenth Amendments. But Amici are unaware of any context wherein it was shown that Congress intended to delegate *to an administrative agency* the power to nullify a state legislative policy, in an area of traditional state regulation, applying a standard of "legitimacy" – measured, not by the Constitution or by reference to conflicting federal enactment, but rather by the policy's acceptance by other States and professional organizations. Merely to state the proposition is to demonstrate its anomaly.

Even if it be assumed that Congress would have the power to make such a delegation of supervisory authority, the delegation must necessarily be unmistakable. And no grant of such authority is evident in the CSA.

[10] In 1998 and 1999, Congress refused passage of a measure to amend the CSA to authorize the United States Attorney General to revoke the registration of practitioners who "intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual." H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998").

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

BILL LOCKYER
Attorney General
of the State of California

TAYLOR S. CAREY
Special Assistant Attorney General

Counsel for Amici States

33

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Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF *AMICUS CURIAE* COALITION OF MENTAL HEALTH PROFESSIONALS IN SUPPORT OF RESPONDENTS

STEVEN ALAN REISS
Counsel of Record
HARRIS J. YALE
SAMANTHA G. FISHERMAN
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, New York 10153
(212) 310-8000

Attorneys for Amicus Curiae
Coalition of Mental Health Professionals

195479

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

Page

TABLE OF CITED AUTHORITIES iii

STATEMENT OF JURISDICTION 1

STATEMENT OF ISSUES 1

STATEMENT OF THE CASE 1

CONSENT OF THE PARTIES 1

INTEREST OF AMICI 1

SUMMARY OF ARGUMENT 8

ARGUMENT 8

I. ADEQUATE DIAGNOSTIC TOOLS AND PROTOCOLS ARE AVAILABLE TO ASSESS THE MENTAL CAPACITY OF A TERMINALLY ILL PATIENT WHO DESIRES TO HASTEN DEATH 8

A. Qualified Personnel Have Adequate Diagnostic Tools to Evaluate Whether a Patient has the Mental Capacity to Exercise Their Rights Under the ODWDA 8

Contents

Page

B. Oregon's Actual Experiences Establish that Mental Capacity Evaluations are Occurring And Not All Requests for Medication Are Being Approved And/Or Used 14

II. A TERMINALLY ILL PATIENT CAN BE CAPABLE OF MAKING A REASONED DECISION TO HASTEN DEATH 16

A. End-of-Life Decisions by Terminally Ill Patients Are Not Equivalent to Suicide by Depressed Individuals 16

B. Many Terminally Ill Patients Are Not Clinically "Depressed." 18

III. INVOLVEMENT OF MENTAL HEALTH PROFESSIONALS IN SITUATIONS INVOLVING END-OF-LIFE DECISION-MAKING, INCLUDING SERVING IN THE ROLE OUTLINED IN THE ODWDA, IS CONSIDERED TO BE APPROPRIATE ... 22

CONCLUSION 28

Appendix — Coalition Members 1a

TABLE OF CITED AUTHORITIES

Page

FEDERAL CASES

Addington v. Texas, 441 U.S. 418 (1979) 10, 12

Compassion in Dying v. Washington, 79 F.3d 790 (9th Cir.), *cert. granted sub nom. Washington v. Glucksberg*, 518 U.S. 1057 (1996), *rev'd*, 521 U.S. 702 (1997) 17

Cooper v. Oklahoma, 517 U.S. 348 (1996) 10, 12

Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990) 10, 12

Medina v. California, 505 U.S. 437 (1992) 10, 12

Oregon v. Ashcroft, 192 F. Supp.2d 1077 (D. Ore. 2002) 9

Vacco v. Quill, 80 F.3d 716 (2d Cir.), *cert. granted*, 518 U.S. 1055 (1996), *rev'd*, 521 U.S. 793 (1997) 5, 17, 27

Washington v. Glucksberg, 521 U.S. 702 (1997) ... 5, 27

Page

STATUTES

O.R.S. 127.800 § 1.01 (3) 9

O.R.S. 127.805 § 2.01 9

O.R.S. 127.820 § 3.02 9

O.R.S. 127.840 § 3.08 13

O.R.S. 127.845 § 3.07 13

O.R.S. 127.850 § 3.08 13

MEDICAL & SCIENTIFIC LITERATURE

2005 ACA Code of Ethics Draft, available at http://www.counseling.org/PDFs/ACA_Code_of_Ethics_2005_Draft.pdf 4, 25

American Psychiatric Association, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 327 (4th ed. 1994) 21

American Psychological Association, TERMINAL ILLNESS AND HASTENED DEATH REQUESTS: THE IMPORTANT ROLE OF THE MENTAL HEALTH PROFESSIONAL (1997) 4, 17

Page

American Psychological Association Working Group on Assisted Suicide and End-of-Life Decisions, *Report to the Board of Directors of the American Psychological Association, Appendix F: Issues to Consider When Exploring End-of-Life Decisions*, REPORT TO THE AMERICAN PSYCHOLOGICAL ASSOCIATION BOARD OF DIRECTORS (2000) 4, 10, 26

Appelbaum & Grisso, *Assessing Patients' Capacities to Consent to Treatment*, 319 NEW ENG. J. MED. 1635 (1988) 13

Back, Starks, Hsu, Gordon, Bharucha & Pearlman, *Clinician-Patient Interactions About Requests for Physician-Assisted Suicide: A Patient and Family View*, 162 ARCH. INT. MED. 1257 (2002) 18

Back, Wallace, Starks & Pearlman, *Physician-Assisted Suicide and Euthanasia in Washington State: Patient Requests and Physician Responses*, 275 J. AM. MED. ASSOC. 919 (1996) 18

Bascom & Tolle, *Responding to Requests for Physician-Assisted Suicide*, 288 J. AM. MED. ASSOC. 91 (2002) 19, 24

Bharucha, Pearlman, Back, Gordon, Starks, & Hsu, *The Pursuit of Physician-Assisted Suicide: Role of Psychiatric Factors*, 6 J. PALL. MED. 873 (2003) 18, 22

Page

Billings & Block, *Palliative Medicine Update: Depression*, 11 J. PALLIATIVE CARE 48 (1995) 21

Block, *Assessing and Managing Depression in the Terminally Ill Patient*, 132 ANN. INTERN. MED. 209 (2000) 21

Breitbart, Rosenfeld, Pessin, Kaim, Funesti-Esch, *et al.*, *Depression, Hopelessness, and Desire for Hastened Death in Terminally Ill Patients with Cancer*, 284 J. AM. MED. ASSOC. 2907 (2000) ... 20

Chochinov, Wilson, Enns, Mowchun, Lander, *et al.*, *Desire for Death in the Terminally Ill*, 152 AM. J. PSYCHIATRY 1185 (1995) 20

Cohen, *Suicide, Hastening Death, and Psychiatry*, 158 ARCH. INTERN. MED. 1973 (1998) 26

Cohen, Steinberg, Hails, Dobscha & Fischel, *Psychiatric Evaluation of Death-Hastening Requests: Lessons from Dialysis Discontinuation*, 41 PSYCHOSOMATICS 195 (2000) 11

Coombs Lee & Werth, *Observations on the First Year of Oregon's Death with Dignity Act*, 6 PSYCHOL., PUBLIC POLICY & L. 268 (2000) 14, 18-19

Page

DiPasquale & Gluck, *Psychologists, Psychiatrists, and Physician-Assisted Suicide: The Relationship Between Underlying Beliefs and Professional Behavior*, 32 PROF. PSYCHOLOGY: RESEARCH & PRACTICE 501 (2001) 23

Drane, *The Many Faces Of Competency*, 15 HASTINGS CENTER REPORT. No. 2, 17 (1985) 13

Emanuel, Fairclough & Emanuel, *Attitudes and Desires Related to Euthanasia and Physician-Assisted Suicide Among Terminally Ill Patients and Their Caregivers*, 284 J. AM. MED. ASSOC. 2460 (2000) 20

Farrenkopf & Bryan, *Psychological Consultation Under Oregon's 1994 Death with Dignity Act: Ethics and Procedures*, 30 PROF. PSYCHOLOGY: RESEARCH & PRACTICE 245 (1999) 9, 24

Fenn & Ganzini, *Attitudes of Oregon Psychologists Toward Physician-Assisted Suicide and the Oregon Death with Dignity Act*, 30 PROF. PSYCHOLOGY: RESEARCH & PRACTICE 235 (1999) ... 23

Freedman, *Competence, Marginal and Otherwise: Concepts and Ethics*, 4 INT'L J. L. & PSYCHIATRY 53 (1981) 13

Ganzini & Dobscha, *If it isn't Depression . . .*, 6 J. PALL. MED. 927 (2003) 19, 22

Page

Ganzini & Dobscha, Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide, 15 J. CLIN. ETHICS, 119 (2004) 15

Ganzini, Dobscha, Heintz & Press, *Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALL. MED. 381 (2003) 15, 18

Ganzini, Fenn, Lee, Heintz & Bloom, *Attitudes of Oregon Psychiatrists Toward Physician-Assisted Suicide*, 153 AM. J. PSYCHIATRY 1469 (2002) 23

Ganzini, Harvath, Jackson, Goy, Miller & Delorit, *Experiences of Oregon Nurses and Social Workers with Hospice Patients who Requested Assistance with Suicide*, 347 NEW ENG. J. MED. 582 (2002) .....*passim*

Ganzini & Lee, *Psychiatry and Assisted Suicide in the United States*, 336 NEW ENG. J. MED. 1824 (1997) 26

Ganzini, Lee & Schmidt, *Letter to the Editor*, 343 NEW ENG. J. MED. 152 (2000) 16

Ganzini, Leong, Fenn, Silva & Weinstock, *Evaluation of Competence to Consent to Assisted Suicide: Views of Forensic Psychiatrists*, 157 AM. J. PSYCHIATRY 595 (2000) 11, 23

Page

Ganzini, Nelson, Schmidt, Kraemer, Delorit & Lee, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW ENG. J. MED. 557 (2000) 14, 15, 18

Hendin & Klerman, *Physician-Assisted Suicide: The Dangers of Legalization*, 150 AM. J. PSYCHIATRY 143 (1993) 16

Jones & Dilley, *Rational Suicide and HIV Disease*, 8 FOCUS: A GUIDE TO AIDS RESEARCH AND COUNSELING (July 1993) 20

Kade, *Death with Dignity: A Case Study*, 132 ANN. INTERN. MED. 504 (2000) 19

Kleespies & Mori, *Life-and-Death Decisions: Refusing Life-Sustaining Treatment*, EMERGENCIES IN MENTAL HEALTH PRACTICE: EVALUATION AND MANAGEMENT (1998) 11

Lavery, Boyle, Dickens, Maclean & Singer, *Origins of the Desire for Euthanasia and Assisted Suicide in People with HIV-1 or AIDS: A Qualitative Study*, 358 LANCET 362 (2001) 18

Miller, Mesler & Eggman, *Take Some Time to Look Inside Their Hearts: Hospice Social Workers Contemplate Physician Assisted Suicide*, 35(3) SOC. WORK IN HEALTH CARE 53 (2002) 24

Page

Mishara, *Synthesis of Research and Evidence on Factors Affecting the Desire of Terminally Ill or Seriously Chronically Ill Persons to Hasten Death*, 39 OMEGA 1 (1999) 20

National Association of Social Workers, *Client Self-Determination in End-of-Life Decisions*, SOCIAL WORK SPEAKS (6th ed. 2003) 4, 6, 10

Ogden & Young, *Euthanasia and Assisted Suicide: A Survey of Registered Social Workers in British Columbia*, 28 BRITISH J. SOC. WORK 161 (1998) ... 24

Oregon Dept. of Human Services, SEVENTH ANNUAL REPORT ON OREGON'S DEATH WITH DIGNITY ACT (2005) 14, 19

Quill & Cassel, *Professional Organizations' Position Statements on Physician-Assisted Suicide*, 138 ANN. INT. MED. 208 (2003) 4

Quill, Coombs Lee & Nunn, *Palliative Treatments of Last Resort: Choosing the Least Harmful Alternative*, 132 ANN. INTERN. MED. 488 (2000) ... 3

Reagan, *Helen*, 353 LANCET 1265 (1999) ... 14, 19

Rogers, Guellette, Abbey-Hines, Carney & Werth, *Rational Suicide: An Empirical Investigation of Counselor Attitudes*, 79 J. COUNSELING & DEVELOPMENT 365 (2001) 24

Page

Rosenfeld, *Assisted Suicide, Depression and the Right to Die*, 6 PSYCHOL., PUB. POLICY & L. 467 (2000) 20

Rosenfeld, Breitbart, Stein, Funesti-Esch, Kaim, *et al., Measuring Desire for Death Among Patients with HIV/AIDS: The Schedule of Attitudes Toward Hastened Death*, 156 AM. J. PSYCHIATRY 94 (1999) 20

Roth, *et al., Tests Of Competency To Consent To Treatment*, 134 AM. J. PSYCHIATRY 279 (1977) ... 13

Smith & Pollack, *A Psychiatric Defense of Aid in Dying*, 34 COMMUNITY MENTAL HEALTH J. 547 (1998) 11

Sullivan, Ganzini & Youngner, *Should Psychiatrists Serve as Gatekeepers for Physician-Assisted Suicide*, HASTINGS CENTER REPORT 24 (July/August 1998) 13

Sullivan & Youngner, *Depression, Competence, and the Right to Refuse Lifesaving Medical Treatment*, 151 AM. J. PSYCHIATRY 971 (1994) 13

Tepper & Elwork, *Competence To Consent To Treatment As A Psycholegal Construct*, 8 LAW & HUMAN BEHAVIOR 205 (1984) 13

Cited Authorities

Page

Tolle, *et al.*, *Characteristics and Proportion of Dying Oregonians Who Personally Consider Physician-Assisted Suicide*, 15 J. CLIN. ETHICS 111 (2004) ... 15

Werth, *The Relationships Among Clinical Depression, Suicide, and Other Actions that may Hasten Death*, 22 BEHAV. SCI. & L. 627 (2004) 18

Werth, *The Appropriateness of Organizational Positions on Assisted Suicide*, 10 ETHICS & BEHAV. 239 (2000) 3

Werth, RATIONAL SUICIDE? IMPLICATIONS FOR MENTAL HEALTH PROFESSIONALS 94 (1996) 13, 23

Werth, Benjamin & Farrenkopf, *Requests for Physician-Assisted Suicide: Guidelines for Assessing Mental Capacity and Impaired Judgment*, 6 PSYCHOL., PUB. POLICY & L. 348 (2000) 9, 13

Werth & Holdwick, *A Primer on Rational Suicide and Other Forms of Hastened Death*, 28 COUNSELING PSYCHOLOGIST 511 (2000) 26

Werth & Liddle, *Psychotherapists' Attitudes Toward Suicide*, 31 PSYCHOTHERAPY: THEORY, RESEARCH & PRACTICE 440 (1994) 23

Cited Authorities

Page

Werth & Wineberg, *A Critical Analysis of Criticisms of the Oregon with Dignity Act*, 29 DEATH STUDIES 1 (2005) 15, 19

Wilson, Scott, Graham, Kozak, Chater, *et al.*, *Attitudes of Terminally Ill Patients Toward Euthanasia and Physician-Assisted Suicide*, 160 ARCH INTERN. MED. 2454 (2000) 20

Wilson, Viola, Scott & Chater, *Talking to the Terminally Ill About Euthanasia and Physician-Assisted Suicide*, 5 CANADIAN J. CLINICAL MED. 68 (April 1998) 18

Wineberg & Werth, *Physician-Assisted Suicide in Oregon: What are the Key Factors?*, 27 DEATH STUDIES 501 (2003) 15, 19

Zaubler & Sullivan, *Psychiatry and Physician-Assisted Suicide*, 19 CONSULTATION-LIAISON PSYCHIATRY 413 (1996) 13

STATEMENT OF JURISDICTION

Amicus, Coalition of Mental Health Professionals, adopts Plaintiffs/Appellees' Statement of Jurisdiction.

STATEMENT OF ISSUES

Amicus, the Coalition, adopts Plaintiffs/Appellees' Statement of Issues.

STATEMENT OF THE CASE

Amicus, the Coalition, adopts Plaintiffs/Appellees' Statement of the case.

CONSENT OF THE PARTIES

This *amicus* brief is filed with the consent of the parties.

INTEREST OF AMICI[1]

This case presents the narrow but important question of whether the Attorney General of the United States has the authority to take an action that will render Oregon's twice-passed Death with Dignity Act ("ODWDA" or the "Act") ineffective. Under this Act, certain terminally ill patients who are Oregon residents may request, and if they meet all criteria, receive, medication that will hasten their death and allow them to

1. This brief has been authored in its entirety by undersigned counsel for the *amicus curiae*. No person or entity, other than the named *amicus* and its counsel, made any monetary contribution to the preparation and submission of this brief. The parties have consented to the filing of this brief and their letters of consent are being lodged herewith.

maintain their mental and emotional dignity in their last days. The Department of Justice ("DOJ"), however, asserts that the Controlled Substances Act (the "CSA") permits the federal government to prevent physicians from assisting patients' exercise of their rights under the ODWDA because the medications are not allegedly being prescribed for a "legitimate medical purpose." DOJ argues that patient utilization of the ODWDA is a threat to public health. DOJ's argument is based, in part, on the erroneous notion that patients choosing to exercise their rights under the ODWDA must be suffering from impaired judgment. This argument nevertheless presumes that mental health issues are an important part of the present case; therefore, the views of mental health professionals such as amici and the weight of research on mental health issues are highly relevant.

The Coalition urges affirmance of the Court of Appeals' decision, and submits that consideration of the question before the Court involves the related issues of the ability to assess: (i) whether adequate diagnostic tools exist to determine the absence or presence of mental capacity and/or impaired judgment, and (ii) whether a terminally ill patient who makes a request under the ODWDA can be capable of making a reasoned decision based on judgment that is unimpaired by a psychiatric or psychological disorder. Amici who submit this brief are an ad hoc group of individual social workers, psychologists, and psychiatrists and related professional groups working as academicians, private practitioners, agency clinicians, administrators, and consultants (the "Coalition"). These mental health professionals have relevant training and experience that makes it appropriate for them to offer their views on terminally ill patients' decision-making capacity in the context of this case.

All individual Coalition members have extensive experience providing psychotherapy, often to persons who are

terminally ill, and/or strong records of research and writing on end-of-life decision-making, depression, grief, or suicide. As mental health professionals, they help patients explore, ameliorate, and/or cope with issues regarding the patient's quality of life. The Coalition submits, however, that supporting the provision of such services to individuals considering hastening death does not signify supporting the hastening of death itself. In fact, it has been argued that organizations comprised of professionals who provide services to clients should ***not take any position*** that explicitly argues for or against "assisted suicide,"[2] but should instead focus on the ways the group's members can help people improve their quality of life and make the best decisions possible given their individual and particular circumstances.[3] A list of Coalition members is attached to this brief as Appendix A.

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2. We place assisted suicide in quotation marks here and elsewhere to indicate that we are using the term (or "rational suicide" when applicable) because it was used by the authors of the sources we cite. However, we agree in principle with the position taken by Quill, Coombs Lee, and Nunn who stated that: ". . . we do not believe the term 'suicide' accurately reflects the meaning of this action, nor does it necessarily differentiate this practice from other last-resort practices. . . . The term 'suicide' also connotes an act of self-destructiveness by a person with mental illness, whereas [in other end-of-life situations], death [can be] viewed by the patients as a form of self-preservation. We must ensure that politicized public discussion about the legalization of physician-assisted suicide does not lead to distortion of the issues and ultimately to uninformed decision making." Quill, Coombs Lee & Nunn, *Palliative Treatments of Last Resort: Choosing the Least Harmful Alternative*, 132 ANN. INTERN. MED. 488, 489 (2000).

3. Werth, *The Appropriateness of Organizational Positions on Assisted Suicide*, 10 ETHICS & BEHAV. 239 (2000). *See also*, National Association of Social Workers, *infra* note 7 and associated text; Washington State Psychological Association, *et al.*, *infra* note 4 and

(Cont'd)

Organizational members of the Coalition are: *Washington State Psychological Association ("WSPA")*, a non-profit professional association of approximately 900 doctoral-level psychologists and other related mental health practitioners. The

(Cont'd)
associated text; American Counseling Association, *2005 ACA Code of Ethics* Draft, available at http://www.counseling.org/PDFs/ACA_Code_of_Ethics_2005_Draft.pdf; American Psychological Association, *infra* note 7; American Psychological Association, *infra* note 22 and associated text. For example, the National Association of Social Workers issued a policy statement in 1994, and reconfirmed it in 1999, entitled "Client Self-Determination in End-of-Life Decisions" which stated that

> social workers should not promote any particular means to end one's life but should be open to full discussion of the issues and care options. . . . Social workers should be free to participate or not participate in assisted-suicide matters or other discussions concerning end-of-life decisions depending on their own beliefs, attitudes, and value systems.

National Association of Social Workers, *infra* note 7, at 48. The American Counseling Association's draft revision of that organization's ethics code contains this section: Quality of Care. Counselors take measures to ensure that clients: (1) receive high quality end-of-life care for their physical, emotional, social, and spiritual needs, (2) have the highest degree of self-determination possible, (3) are given every opportunity possible to engage in informed decision making regarding their end-of-life care, and (4) receive complete and adequate assessment regarding their ability to make competent, rational decisions on their own behalf from a mental health professional who is experienced in end-of-life care practice; see also infra note 43 and accompanying text. A similar position was taken by Quill and Cassel, who argued that medical associations should take "a position of studied neutrality" on "physician-assisted suicide." *Professional Organizations' Position Statements on Physician-Assisted Suicide*, 138 ANN. INT. MED. 208, 210 (2003).

WSPA's mission is to support, promote, and advance the science and practice of psychology in the public interest. Many WSPA members work with clients who are considering end-of-life decisions and assist terminally ill patients and their families with their problems on a regular basis. WSPA members routinely assess the mental capacity, the possibility of impaired judgment, and the presence of clinical depression among many clients, including those who are terminally ill and those contemplating suicide. The WSPA filed an *amicus curiae* brief with the U.S. Supreme Court in the two "assisted suicide" cases, *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997).[4]

Oregon Psychological Association ("OPA"). OPA is a non-profit professional association of approximately 840 doctoral-level psychologists and other related mental health practitioners. The OPA joins this Brief to underscore the scientific support for determining competence, impaired judgment, and clinical depression for patients who are terminally ill and for the subgroup of patients who may contemplate using the ODWDA. Many OPA members work with clients who are considering end-of-life decisions and assist terminally ill patients and their families with their problems on a regular basis. OPA members routinely assess the mental capacity, the possibility of impaired judgment, and the presence of clinical depression among many clients, including those who are terminally ill and those

4. Brief *Amici Curiae* for the Washington State Psychological Association, *et al.*, in *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997). The WSPA's briefs focused on the roles mental health professionals could play in situations involving "assisted suicide" (rather than arguing that it should be a constitutional right), because the mental capacity of terminally ill individuals can be reliably assessed – the same reasons why it has signed on to the present Brief.

contemplating suicide. By reason of the skills, training, and experience of its members, OPA can provide meaningful insight into the mental capacity of terminally ill patients and into the diagnostic and evaluative resources available to verify such capacity.

National Association of Social Workers. With 153,000 members, the National Association of Social Workers ("NASW") is the largest organization of professional social workers in the world. Created in 1955, the purposes of NASW include improving the quality and effectiveness of social work practice in the United States and developing and disseminating high standards of social work practice, concomitant with the strengthening and unification of the social work profession as a whole. In furtherance of these purposes, NASW promulgates professional standards and criteria. Additionally, NASW conducts research, prepares studies of interest to the profession, and enforces the NASW Code of Ethics, which NASW members are required to honor. NASW's members are highly trained and experienced professionals who counsel individuals, families, and communities in a variety of settings, including schools, hospitals, mental health clinics, senior centers, and private practices. The practice of social work requires knowledge of human development and behavior; social, economic and cultural institutions; and of the interaction of all of these factors. The NASW policy, Client Self-Determination in End-of-Life Decisions, states "Social workers have an important role in helping individuals identify the end-of-life-options available to them. . . . A key value for social workers is client self-determination. Competent individuals should have the opportunity to make their own choices but only after being informed of all options and consequences. . . . without coercion." Social Work Speaks: NASW Policy Statements (2003 - 2006).

Oregon Chapter, National Association of Social Workers. This is a professional association with approximately 1,700 members in Oregon, affiliated with the NASW. Most members have advanced degrees (at least master's level) in social work. Oregon Chapter NASW members are involved in hospice care and end-of-life decisions for their clients, including decisions related to ODWDA. The national association has adopted a strong policy statement in favor of client self-determination in end-of-life decisions, which is binding upon and supported by the Oregon Chapter. As advocates and counselors for their clients, Oregon Chapter NASW members have interest and expertise in issues concerning end-of-life decisions, including the mental status of terminally ill patients.

Clinical Social Work Federation ("CSWF"). A non-profit professional organization of approximately 3000 members, the CSWF membership is comprised of licensed or certified clinical social workers with MSW, or PhD./DSW degrees. Members of the CSWF provide mental health services for the diagnosis, treatment, and prevention of mental, behavioral, and emotional disorders. Members work in a variety of settings including those that serve terminally ill individuals and their families and those contemplating end-of-life decision making for other reasons. Clinical social workers have the ability to determine mental capacity, impaired judgment, and executive functioning, and to diagnose clinical depression. The CSWF does not adhere to the belief that either terminal illness or clinical depression prevents an individual from making informed decisions.

Amici offer the following observations to assist the Court in ruling on the important questions presented in this case.

SUMMARY OF ARGUMENT

The ODWDA was approved by the voters of Oregon to allow an opportunity for terminally ill patients to end their lives with dignity and respect. The DOJ assertion that the CSA permits the federal government to deprive the citizens of Oregon from exercising its rights under the ODWDA because such law presents a risk to the public health is seriously flawed. The DOJ's argument is based, in part, on the erroneous idea that patients choosing to exercise such rights must be suffering from impaired judgment. However, not all terminally ill patients are mentally impaired and it is possible for some terminally ill patients to make a reasoned decision that is not a product of depression or psychiatric illness to hasten their death and end their lives with dignity.

ARGUMENT

I. ADEQUATE DIAGNOSTIC TOOLS AND PROTOCOLS ARE AVAILABLE TO ASSESS THE MENTAL CAPACITY OF A TERMINALLY ILL PATIENT WHO DESIRES TO HASTEN DEATH

A. Qualified Personnel Have Adequate Diagnostic Tools to Evaluate Whether a Patient has the Mental Capacity to Exercise Their Rights Under the ODWDA.

In order to receive medication under the ODWDA, a terminally ill Oregon resident must follow a specific and detailed procedure and must be deemed "capable" by the attending physician and a consulting physician, or, if a referral is made by one of those physicians for further mental health evaluation, a licensed psychologist or psychiatrist. The Act clearly provides

that any patient wishing to exercise their rights under the Act must demonstrate the requisite capacity and sets forth how this is to be shown. O.R.S. 127.805 § 2.01; 127.820 at § 3.02; 127.800 at § 1.01 (3). If there is any question about the patient's capacity to request medication under the ODWDA, because the patient may be suffering from impaired judgment, the statute explicitly requires that a licensed psychologist or psychiatrist be consulted, and prohibits any medication from being prescribed until a determination regarding the presence or absence of impaired judgment is made. O.R.S. 127.805 § 2.01. The statute itself builds in a first-level safeguard to ensure that if there is a question about mental capacity being impaired by psychological or psychiatric disorder, no medication shall be given until an assessment is performed by a licensed psychologist or psychiatrist.[5]

The Coalition respectfully submits that the weight of scientific and medical research supports the proposition that adequate diagnostic tools exist for mental health professionals to assess the mental capacity of a terminally ill patient. Detailed protocols are available for evaluating a patient's capacity and potentially impaired judgment, including guidance specifically for use with the ODWDA.[6] Such protocols and tools allow trained and qualified professionals to assess the accuracy of the patient's understanding of his or her medical condition, including

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5. *Id.*; *see also Oregon v. Ashcroft*, 192 F. Supp.2d 1077, 1081-82 (D. Or. 2002).

6. Farrenkopf & Bryan, *Psychological Consultation Under Oregon's 1994 Death with Dignity Act: Ethics and Procedures*, 30 PROF. PSYCHOLOGY: RESEARCH & PRACTICE 245 (1999); Werth, Benjamin & Farrenkopf, *Requests for Physician-Assisted Suicide: Guidelines for Assessing Mental Capacity and Impaired Judgment*, 6 PSYCHOL., PUB. POLICY & L. 348 (2000).

the prognosis and treatment alternatives; review the quality of the patient's deliberative process; identify the presence of major depression or another psychological condition; and, therefore, evaluate the soundness of the patient's decision.[7]

Mental health professionals who have the requisite training, experience, and direct contact with an individual patient are in a position to make such an evaluation and assess whether a patient has the capacity to make a reasoned end-of-life decision.[8]

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7. Reflective of the fact that many mental health professionals believe that people can make well-reasoned decisions that death is their best option, whether assisted by a physician or not, some of these assessment outlines have been developed by national mental health organizations or working groups of such organizations. *See* American Psychological Association Working Group on Assisted Suicide and End-of-Life Decisions, *Report to the Board of Directors of the American Psychological Association, Appendix F: Issues to Consider When Exploring End-of-Life Decisions*, in REPORT TO THE AMERICAN PSYCHOLOGICAL ASSOCIATION BOARD OF DIRECTORS 79-86 (2000); National Association of Social Workers, *Client Self-Determination in End-of-Life Decisions*, in SOCIAL WORK SPEAKS: NATIONAL ASSOCIATION OF SOCIAL WORKERS POLICY STATEMENTS, 2003-2006 46 (6th ed. 2003).

8. Tnis Court has commented that "the subtleties and nuances of psychiatric diagnosis render certainties virtually beyond reach in most situations." *Medina v. California*, 505 U.S. 437, 451 (1992), *quoting Addington v. Texas*, 441 U.S. 418, 430 (1979); *see also Cooper v. Oklahoma*, 517 U.S. 348, 365-66 (1996). In this context as in other areas of law (or medicine), however, the impossibility of certainty does not obviate the need to evaluate the mental state of the patient. *Id.* The nature of end-of-life decisions would certainly justify use of a standard under which close cases are resolved in favor of preserving the medical status quo. *See Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 283 (1990). But the inevitability of close cases cannot, by itself, justify imposing a flat prohibition that will apply even in cases where the evidence of mental capacity is clear.

Such evaluations are typical and common in the practice of mental health professionals.[9] Indeed, "psychiatrists and other physicians [as well as psychologists, social workers, and other qualified mental health professionals] have been successfully conducting such evaluations for years when persons request discontinuation of life sustaining treatment."[10] Moreover, such assessments commonly arise in a variety of legal contexts, from

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9. Many mental health professionals have extensive experience in making both formal written evaluations and ongoing, informal assessments of decision-making capacity and rationality during the course of psychotherapy, counseling, or psychiatric consultation in medical settings. Indeed, professional evaluation occurs continuously during therapy and within the context of hospital or outpatient consultations.

10. Smith & Pollack, *A Psychiatric Defense of Aid in Dying*, 34 COMMUNITY MENTAL HEALTH J. 547 (1998). *See also* Kleespies & Mori, *Life-and-Death Decisions: Refusing Life-Sustaining Treatment*, in EMERGENCIES IN MENTAL HEALTH PRACTICE: EVALUATION AND MANAGEMENT at 145 (1998); Cohen, Steinberg, Hails, Dobscha & Fischel, *Psychiatric Evaluation of Death-Hastening Requests: Lessons from Dialysis Discontinuation*, 41 PSYCHOSOMATICS 195 (2000); Ganzini, Leong, Fenn, Silva & Weinstock, *Evaluation of Competence to Consent to Assisted Suicide: Views of Forensic Psychiatrists*, 157 AM. J. PSYCHIATRY 595, 597 (2000) (surveyed Board-certified members of the American Academy of Psychiatry and the Law and found that 74% of the respondents "had evaluated the competence of a patient whose refusal of treatment would have resulted in the patient's death"). Although it is certainly true that psychologists and psychiatrists may be asked to make assessments of mental capacity in situations where other end-of-life decisions are being made (*e.g.*, discontinuation of life support), in such situations there is no mandatory requirement for a mental health assessment nor that a diagnosable depression be ruled out before the patient's wishes can be acted upon.

competence to stand trial to competence to make a valid will.[11] In deciding the legal issue of "competence" in these contexts, courts have inevitably relied upon the training, experience, and expert judgment of qualified mental health professionals to assess a given individual's capacity to make reasoned decisions.[12]

Although the particular legal standard of competence varies depending upon the rights and interests at stake in a given context,[13] there is no dispute that such standard may appropriately be set at a high level for assessing decision-making capacity in the end-of-life context.[14] The mental health literature suggests that one appropriate standard for determining capability would require that a terminally ill patient be able to:

> (a) understand and remember information relevant to an end-of-life decision;
>
> (b) appreciate the consequences of the decision;

11. *See, e.g., Cooper*, 517 U.S. at 348 (competence to stand trial); *Addington* 441 U.S. at 418 (involuntary civil commitment).

12. *See, e.g., Medina*, 505 U.S. at 450. *See also Addington*, 441 U.S. at 465 (Blackmun, J., dissenting).

13. *See, e.g., Cooper*, 517 U.S. at 367-68 (contrasting standards for involuntary commitment and for competence to stand trial).

14. *Cf. Cruzan*, 497 U.S. at 282-284 (1990); *Addington*, 441 U.S. at 423 ("The function of a standard of proof . . . is to 'instruct the factfinder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication.'") (quoting *In re Winship*, 397 U.S. 358, 370 (1970) (Harlan, J., concurring).

> (c) indicate a clearly held and consistent underlying set of values that provide some guidance in making the decision; and
>
> (d) communicate the decision and explain the process used for making it.[15]

Using these criteria, a mental health professional evaluating decision-making capacity would examine a patient's "chain of reasoning," and would seek to determine whether the patient can "indicate the major factors in his decisions and the importance assigned to them."[16] Similar requirements are set out multiple times under the Act, mandating that a patient, among other things, make "an oral request and a written request, and reiterate the oral request to his or her attending physician no less than fifteen (15) days after making the initial oral request" (O.R.S. 127.850 § 3.08, O.R.S. 127.840 § 3.08), and be given an opportunity to rescind the request (O.R.S. 127.845 § 3.07).

15. Werth, *et al., supra* note 6. *See also, e.g.*, Drane, *The Many Faces Of Competency*, 15 HASTINGS CENTER REPORT No. 2, 17, 19 (1985); Freedman, *Competence, Marginal and Otherwise; Concepts and Ethics*, 4 INT'L J. L. & PSYCHIATRY 53, 59-60 (1981); Roth, *et al., Tests Of Competency To Consent To Treatment*, 134 AM. J. PSYCHIATRY 279, 280-282 (1977); Sullivan, Ganzini & Youngner, *Should Psychiatrists Serve as Gatekeepers for Physician-Assisted Suicide*, HASTINGS CENTER REPORT 24 (July/Aug 1998); Sullivan & Youngner, *Depression, Competence, and the Right to Refuse Lifesaving Medical Treatment*, 151 AM. J. PSYCHIATRY 971 (1994); Tepper & Elwork, *Competence To Consent To Treatment As A Psycholegal Construct*, 8 LAW & HUMAN BEHAVIOR 205; Werth, RATIONAL SUICIDE? IMPLICATIONS FOR MENTAL HEALTH PROFESSIONALS 94 (1996); Zaubler & Sullivan, *Psychiatry and Physician-Assisted Suicide*, 19 CONSULTATION-LIAISON PSYCHIATRY 413 (1996).

16. Appelbaum & Grisso, *Assessing Patients' Capacities to Consent to Treatment*, 319 NEW ENG. J. MED. 1635, 1636 (1988).

Thus, the diagnostic tools for an effective evaluation exist, and qualified professionals are able to use them to make this evaluation regarding a terminally ill patient's mental capacity. The expertise of and tools available to physicians and mental health professionals work cohesively with the safeguards incorporated into the ODWDA to allow those terminally ill patients who possess unimpaired judgment to exercise their rights and maintain their dignity throughout their lives.

B. Oregon's Actual Experiences Establish that Mental Capacity Evaluations are Occurring And Not All Requests for Medication Are Being Approved And/ Or Used.

Oregon's actual experience with ODWDA demonstrates that capacity evaluations are being performed, and that not all requests for medication are approved, and of those approved, not all are ultimately used.[17] In a survey of Oregon physicians

17. The ODWDA has been in effect since late 1997 and seven annual official reports have been issued by the Oregon Health Division. In 2004, the most recent year for which the Oregon Health Division has released statistics, 60 physician prescriptions for such medication were written, but only 37 individuals ingested medication prescribed under the provisions of ODWDA. *See* Oregon Dept. of Human Services, SEVENTH ANNUAL REPORT ON OREGON'S DEATH WITH DIGNITY ACT (2005). Each of these individuals had to be screened by an attending physician and a consulting physician to ensure that the individual's judgment was not impaired by psychological or psychiatric disorder, as required by the statute. *Id. See also* Coombs Lee & Werth, *Observations on the First Year of Oregon's Death with Dignity Act*, 6(2) PSYCHOL., PUBLIC POLICY & L. 268 (2000); Ganzini, Nelson, Schmidt, Kraemer, Delorit & Lee, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW ENG. J. MED. 557 (2000); Reagan, *Helen*, 353 LANCET 1265 (1999); Ganzini, Harvath, Jackson, Goy, Miller & Delorit, *Experiences* (Cont'd)

who had experience with the ODWDA, responses indicated that 165 people had requested medication under the Act from these physicians during the first two years the law was in effect.[18] Of these 165, only 29 (18%) actually received a prescription, and of these 29, only 17 individuals used it.[19]

The survey also demonstrates that physicians are making determinations of ineligibility based on impaired judgment – they are not freely writing prescriptions to every patient who asks for it. Physicians reported that 17% of the individuals requesting medication had "a mental disorder such as depression which impaired his/her judgment." None of those patients were given a prescription under the Act. The results of the study led the authors to conclude that "[the] data simply do not support the hypothesis that among patients eligible for assistance with suicide under the [ODWDA], vulnerable groups, including mentally ill patients, request assistance with suicide

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of Oregon Nurses and Social Workers with Hospice Patients who Requested Assistance with Suicide, 347 NEW ENG. J. MED. 582 (2002); Ganzini, Dobscha, Heintz & Press, *Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALL. MED. 381 (2003); Wineberg & Werth, *Physician-Assisted Suicide in Oregon: What are the Key Factors?*, 27 DEATH STUDIES 501 (2003); Werth & Wineberg, *A Critical Analysis of Criticisms of the Oregon with Dignity Act*, 29 DEATH STUDIES 1 (2005); Tolle, *et al.*, *Characteristics and Proportion of Dying Oregonians Who Personally Consider Physician-Assisted Suicide*, 15 J. CLIN. ETHICS 111 (2004); Ganzini & Dobscha, Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide, 15 J. CLIN. ETHICS, 119 (2004).

18. Ganzini, Nelson, *et al.*, *supra* note 17.

19. *Id.*

disproportionately or receive lethal prescriptions in place of palliative care."[20]

ODWDA creates a system in which only adults who are capable of making a reasoned judgment about their desire to make a request under the Act and the consequences thereof are eligible for the option provided thereunder, and those with impaired judgment may be determined and screened from receiving the requested medication.

II. A TERMINALLY ILL PATIENT CAN BE CAPABLE OF MAKING A REASONED DECISION TO HASTEN DEATH

Defendants' argument regarding an alleged threat to public health rests upon an erroneous comparison of hastened death under the ODWDA to "suicide," and an erroneous assumption that a terminally ill patient's decision to hasten death must be the result of a mental disorder which impairs judgment.

A. End-of-Life Decisions by Terminally Ill Patients Are Not Equivalent to Suicide by Depressed Individuals.

Using a model of suicide as the proxy for a desire to hasten death is extremely problematic, given the assumption of irrationality due to mental illness in instances of suicide. Even those who oppose "assisted suicide" acknowledge that a blanket statement cannot be made about people who may want to hasten death when they are dying of a terminal illness.[21]

20. Ganzini, Lee & Schmidt, *Letter to the Editor*, 343 NEW ENG. J. MED. 152, 152 (2000).

21. *See, e.g.*, Hendin & Klerman, *Physician-Assisted Suicide: The Dangers of Legalization*, 150 AM. J. PSYCHIATRY 143, 145 (1993) ("We are likely to find that those who seek to die in the last days of terminal illness are a quite different population from those whose first response to the knowledge of serious illness is to turn to suicide.").

End-of-life decisions by terminally ill patients are not akin to what is commonly termed "suicide," which is considered to be a self-destructive act often related to feelings of depression. These decisions to hasten death are more accurately paralleled to a patient's thoughtful decision to decline life-sustaining measures: a product of judgment and reason, based on the desire to maintain one's dignity in a period where death in pending. A working group of the American Psychological Association stated that: "It is important to remember that the reasoning on which a terminally ill person (whose judgments are not impaired by mental disorders) bases a decision to end his or her life is fundamentally different from the reasoning a clinically depressed person uses to justify suicide."[22] In contrast to suicide, refusal of life-sustaining treatment by terminally ill patients is often seen as an affirmation of their dignity in a fully lived life, a concept that many states, including Oregon, have already deemed worthy of legal recognition.[23]

Thus, medical and scientific research have found that many individuals facing certain death, along with the possibility of physical pain and loss of dignity – which are not factors for those who choose to commit suicide in response to emotional and mental distress – may desire to hasten death free from judgment impaired by depression or other mental disorder. The comparison to "suicide" is simply inapposite.

22. American Psychological Association, TERMINAL ILLNESS AND HASTENED DEATH REQUESTS: THE IMPORTANT ROLE OF THE MENTAL HEALTH PROFESSIONAL 1 (1997).

23. *See, e.g., Compassion in Dying v. Washington*, 79 F.3d 790, 817-20 (9th Cir.), *cert. granted*, 518 U.S. 1055 (1996), *rev'd*, 521 U.S. 793 (1997); *Vacco v. Quill*, 80 F.3d 716, 727-28 (2d Cir.), *cert. granted sub nom. Washington v. Glucksberg*, 518 U.S. 1057 (1996), *rev'd*, 521 U.S. 702 (1997).

B. Many Terminally Ill Patients Are Not Clinically "Depressed."

The weight of medical and mental health research and experience indicates that terminally ill people who have a desire for death in general, or, more particularly, who wish to hasten death through use of the ODWDA, are not incapable of making healthcare decisions, suffering from impaired judgment, or experiencing major depression.[24] In fact, research and experience demonstrate that a personal sense of autonomy, control, and dignity are typically the most influential reasons why terminally ill people in general want to hasten death[25] and why terminally ill Oregonians want to use the ODWDA.[26] Based on their

24. Werth, *The Relationships Among Clinical Depression, Suicide, and Other Actions that may Hasten Death*, 22 BEHAV. SCI. & L. 627 (2004).

25. Back, Wallace, Starks, & Pearlman, *Physician-Assisted Suicide and Euthanasia in Washington State: Patient Requests and Physician Responses*, 275 J. AM. MED. ASSOC. 919 (1996); Lavery, Boyle, Dickens, Maclean & Singer, *Origins of the Desire for Euthanasia and Assisted Suicide in People with HIV-1 or AIDS: A Qualitative Study*, 358 LANCET 362, 362 (2001) (for 32 people with HIV disease "Euthanasia and assisted suicide were seen by participants as a means of limiting loss of self."); Wilson, Viola, Scott & Chater, *Talking to the Terminally Ill About Euthanasia and Physician-Assisted Suicide*, 5 CANADIAN J. CLINICAL MED. 68 (April 1998); Back, Starks, Hsu, Gordon, Bharucha, & Pearlman, *Clinician-Patient Interactions About Requests for Physician-Assisted Suicide: A Patient and Family View*, 162 ARCH. INT. MED. 1257 (2002); Bharucha, Pearlman, Back, Gordon, Starks, & Hsu, *The Pursuit of Physician-Assisted Suicide: Role of Psychiatric Factors*, 6 J. PALL. MED. 873 (2003); Werth, supra note 24.

26. Ganzini, Nelson, *et al.*, *supra* note 17; Ganzini, Harvath, *et al.*, *supra* note 17; Ganzini, Dobscha, *et al.*, *supra* note 17; Coombs

(Cont'd)

experience with many individuals who have died of terminal illnesses, and upon the scientific and medical research available, the Coalition strongly opposes the assertion that a terminally ill patient's desire to hasten death necessarily involves depression or other mental disorder.[27]

Indeed, medical and scientific studies confirm that unlike with suicide, many terminally ill patients can and do make "rational" decisions, free of depressive or other mental disorder, regarding whether or not to hasten death. For example,[28] in one

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Lee & Werth, *supra* note 17; Reagan, *supra* note 17; Wineberg & Werth, *supra* note 17; Werth & Wineberg, *supra* note 17; Oregon Dept. of Human Services, *supra* note 16; Kade, *Death with Dignity: A Case Study*, 132 ANN. INTERN. MED. 504 (2000); Ganzini & Dobscha, *If it isn't Depression . . .*, 6 J. PALL. MED. 927 (2003); Bascom & Tolle, *Responding to Requests for Physician-Assisted Suicide*, 288 J. AM. MED. ASSOC. 91 (2002); L. Ganzini, personal communication by e-mail to J. Werth, Jr., January 7, 2002.

27. Thus, the description of the case of Michael P. Freeland, set forth in an appendix to the amicus brief of Physicians for Compassionate Care Educational Foundation, is fundamentally flawed for at least two reasons. First, there is no external verification of incapacity or impaired judgment; in fact, several physicians determined Mr. Freeland had capacity, and an attempt to have him ruled incompetent was dropped after the discovery phase. Second, the description glosses over the fact that Mr. Freeland died of natural causes, without taking the medication prescribed under ODWDA – the very choice the ODWDA is intended to provide. We are confident that more thorough rebuttals of the claims in that Appendix will appear in the professional literature.

28. For examples of other recent studies that examined the presence of diagnosable depression among terminally ill individuals who desired a hastened death – all of which found that a significant percentage were

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study, only 31 of 159 terminally ill patients who had an interest in "physician-assisted suicide" or euthanasia were considered to be depressed; only 2 of 11 patients who had discussed euthanasia or "physician-assisted suicide," collected medication for "assisted suicide," or had caregivers discuss euthanasia with physicians had "depressive symptoms."[29] In one survey of 39 HIV-positive individuals, researchers concluded that more than two-thirds had rationally contemplated ending their life and that the desire to hasten death was not directly related to clinical depression as measured by the Beck Depression Inventory (the most widely used rapid screening test for the presence of major depression).[30] Depression is a distinct and serious disorder that

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not depressed – *See* Breitbart, Rosenfeld, Pessin, Kaim, Funesti-Esch, *et al.*, *Depression, Hopelessness, and Desire for Hastened Death in Terminally Ill Patients with Cancer*, 284 J. AM. MED. ASSOC. 2907 (2000); Chochinov, Wilson, Enns, Mowchun, Lander, *et al.*, *Desire for Death in the Terminally Ill*, 152 AM. J. PSYCHIATRY 1185 (1995); Rosenfeld, Breitbart, Stein, Funesti-Esch, Kaim, *et al.*, *Measuring Desire for Death Among Patients with HIV/AIDS: The Schedule of Attitudes Toward Hastened Death*, 156 AM. J. PSYCHIATRY 94 (1999); Wilson, Scott, Graham, Kozak, Chater, *et al.*, *Attitudes of Terminally Ill Patients Toward Euthanasia and Physician-Assisted Suicide*, 160 ARCH. INTERN. MED. 2454 (2000). *See also* Mishara, *Synthesis of Research and Evidence on Factors Affecting the Desire of Terminally Ill or Seriously Chronically Ill Persons to Hasten Death*, 39 OMEGA 1 (1999); Rosenfeld, *Assisted Suicide, Depression and the Right to Die*, 6 PSYCHOL., PUB. POLICY & L. 467 (2000).

29. Emanuel, Fairclough & Emanuel, *Attitudes and Desires Related to Euthanasia and Physician-Assisted Suicide Among Terminally Ill Patients and Their Caregivers*, 284 J. AM. MED. ASSOC. 2460, 2464, 2467 (2000).

30. Jones & Dilley, *Rational Suicide and HIV Disease*, 8 FOCUS: A GUIDE TO AIDS RESEARCH AND COUNSELING 5 (July 1993).

can be identified and diagnosed.[31] The American Psychiatric Association's DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS lists nine criteria for identifying a Major Depressive Episode.[32] Under the diagnostic model, five of these criteria — one of which must be either depressed mood or loss of interest or pleasure — must manifest during any single two-week period. If fewer than five criteria are present, or they do not occur within this time frame, then "depression," as a psychological disorder, is not present.[33]

Scientific and medical research establish that it is not appropriate to assume that any decision to hasten death must be motivated by depression or other mood disorders. Indeed, in a variety of studies of terminally ill patients, a majority of those studies found that less than half of the terminally ill patients studied could be diagnosed with major depression.[34] At the very least, a large group of individuals who might medically qualify under the ODWDA were not suffering from judgment impaired by depression. Moreover, a recent study of hospice nurses and social workers in Oregon led the lead author to conclude that "the data do not support that depression is an important

31. For example, the literature shows that clear distinctions can be made between depression and grief. *See* Block, *Assessing and Managing Depression in the Terminally Ill Patient*, 132 ANN. INTERN. MED. 209 (2000).

32. American Psychiatric Association, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 327 (4th ed. 1994).

33. Billings & Block, *Palliative Medicine Update: Depression*, 11 J. PALLIATIVE CARE 48, 48 (1995).

34. Block, *supra*, note 31.

contributor in patients who received a lethal prescription."[35] Similarly, a study in Washington examining the role of clinical depression and other psychiatric conditions on a person's pursuit of physician-assisted suicide found that depressive symptoms did not appear to be an influential factor in decision-making and none of the participants appeared to have depression-related decisional incapacity.[36]

Thus, an assumption that all terminally ill patients are per se suffering from major depression is simply unsupportable and no blanket statements regarding their judgment properly can be made.

III. INVOLVEMENT OF MENTAL HEALTH PROFESSIONALS IN SITUATIONS INVOLVING END-OF-LIFE DECISION-MAKING, INCLUDING SERVING IN THE ROLE OUTLINED IN THE ODWDA, IS CONSIDERED TO BE APPROPRIATE

Because psychologists and psychiatrists are specified in the ODWDA as the professionals to whom the attending or consulting physician must refer a person if either of them has concerns about the possible presence of impaired judgment, the viewpoints of Oregon psychologists and psychiatrists concerning the ODWDA are important to consider. A survey of Oregon

35. L. Ganzini, personal communication by e-mail to J. Werth, Jr., January 7, 2002. *See* Ganzini, Harvath, *et al.*, *supra*, note 17 at 582 ("A very important reason for the request [to use the ODWDA] was to control the circumstances of death. The least important reasons included depression, lack of social support, and fear of being a financial drain on family members.").

36. Bharucha et al, *supra*, note 25; Ganzini & Dobscha, *supra*, note 26.

psychiatrists found that two-thirds of the respondents "endorsed the view that a physician should be permitted, under some circumstances, to write a prescription for a medication whose sole purpose would be to allow a patient to end his or her life."[37] A more recent survey of Oregon psychologists found that 78% supported the enactment of the ODWDA and 91% supported both "rational" and physician-"assisted suicide" more generally.[38] Thus, a significant percentage of psychologists and psychiatrists in Oregon believe that a decision by a terminally ill patient to hasten his or her own death may be carefully considered and fully rational.[39]

37. Ganzini, Fenn, Lee, Heintz & Bloom, *Attitudes of Oregon Psychiatrists Toward Physician-Assisted Suicide*, 153 AM. J. PSYCHIATRY 1469, 1469 (1996).

38. Fenn & Ganzini, *Attitudes of Oregon Psychologists Toward Physician-Assisted Suicide and the Oregon Death with Dignity Act*, 30 PROF. PSYCHOLOGY: RESEARCH & PRACTICE 235, 236, 237 (1999).

39. These attitudes are similar to those found in other surveys of psychologists, counselors, and social workers. *See, e.g.*, DiPasquale & Gluck, *Psychologists, Psychiatrists, and Physician-Assisted Suicide: The Relationship Between Underlying Beliefs and Professional Behavior*, 32 PROF. PSYCHOLOGY: RESEARCH & PRACTICE 501 (2001) (75% of responding psychologists and psychiatrists in New Mexico thought physician-"assisted suicide" should be legal); Ganzini, *et al.*, *supra* note 10 at 597 (80% of respondents thought suicide was ethical in some or all circumstances, 66% believed physician-"assisted suicide" was ethical); Werth & Liddle, *Psychotherapists' Attitudes Toward Suicide*, 31 PSYCHOTHERAPY: THEORY, RESEARCH & PRACTICE 440 (1994) (81% of the respondents from a national sample of the American Psychological Association's Division of Psychotherapy stated that they believed that an individual could make a rational decision to die by "suicide"); Werth, *supra* note 15 at 47 (86% of the respondents to a survey of members of the National Register of Health Service Providers in Psychology believed

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In addition, Oregon mental health professionals believe that they can provide appropriate and effective services under the ODWDA and guidelines have been provided for their use in such situations.[40] Similarly, several organizations representing mental health professionals have taken positions that support the involvement of their members in providing services to individuals who are making end-of-life decisions, including considering whether to request and receive medication such as is offered under the ODWDA; however, as noted at the beginning of this Brief, supporting involvement should not be necessarily interpreted as support for assisted suicide in general or the ODWDA in particular.

In 1998, the American Psychological Association ("APA") convened a Working Group on Assisted Suicide and End-of-Life Decisions which issued an extensive Report to the Board

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in "rational suicide"); Rogers, Guellette, Abbey-Hines, Carney & Werth, *Rational Suicide: An Empirical Investigation of Counselor Attitudes*, 79 J. COUNSELING & DEVELOPMENT 365 (2001) (surveyed members of the American Mental Health Counselors Association and found 81% of respondents believed in the idea of "rational suicide"); Ogden & Young, *Euthanasia and Assisted Suicide: A Survey of Registered Social Workers in British Columbia*, 28 BRITISH J. SOC. WORK 161 (1998) (nearly 80% of responding social workers believed that "assisted suicide" should be legal in some circumstances); Ganzini, Harvath, *et al.*, *supra* note 17 (66% of hospice social workers support or strongly support the ODWDA, only 12% oppose or strongly oppose); Miller, Mesler & Eggman, *Take Some Time to Look Inside Their Hearts: Hospice Social Workers Contemplate Physician Assisted Suicide*, 35(3) SOC. WORK IN HEALTH CARE 53 (2002).

40. Farrenkopf & Bryan, *supra* note 6; Werth, *et al.*, *supra* note 6; Bascom & Tolle, *supra* note 26.

of Directors two years later.[41] In 2001, the APA passed a resolution, which neither endorsed nor opposed "assisted suicide," but stated that "psychologists have many areas of competence, including assessment, counseling, teaching, consultation, research, and advocacy skills that could potentially enlighten the discourse about "assisted suicide," end-of-life treatment, and support for dying persons and their significant others."[42]

Similarly, in the American Counseling Association's *2005 ACA Code of Ethics Draft*, there is a new section entitled "End-of-Life Care for Terminally Ill Clients" that includes sections on Quality of Care; Counselor Competence, Choice, and Referral; and Confidentiality.[43] Regarding competence, the organization stated, "Recognizing the personal, moral, and competence issues related to end-of-life decisions, counselors may choose to work or not work with terminally ill clients who wish to explore their end-of-life options. . . ." Specifically related to assisted death, in the Confidentiality section, the draft code

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41. Available at http://www.apa.org/pi/aseolf.html.

42. In the "assisted suicide" resolution, it was further resolved that the APA should

> Encourage psychologists to identify factors leading to assisted suicide requests (including clinical depression, levels of pain and suffering, adequacy of comfort care, and other internal and external variables) and to fully explore alternative interventions (including hospice/palliative care, and other end-of-life options such as voluntarily stopping eating and drinking) for clients considering assisted suicide.

Id.

43. American Counseling Association, *supra* note 3; see also note 3 for the entire Quality of Care section.

specifies that, "Counselors who provide services to terminally ill individuals who are considering hastening their own deaths have the option of breaking or not breaking confidentiality, depending on the specific circumstances of the situation and after seeking consultation or supervision."

It is clear that individual mental health professionals and several of their professional associations allow involvement in situations where clients are considering end-of-life issues, including "assisted suicide." A mental health professional can not only conduct an evaluation for capacity or impaired judgment to satisfy the letter of the law, but can also assist in identifying and ameliorating issues that are compromising the quality of life of the dying person and her or his loved ones.[44] Professionals can, for example, help patients address issues such as pain, depression, dignity, tranquility, financial concerns, and the effectiveness or futility of available medical treatments; communicate with other health care providers, family members, social service providers, or others concerning the patient's needs, concerns, and preferences, to help ensure that the patient receives necessary support and that the treatment provided comports with the patient's wishes; and promote and monitor appropriate involvement by significant others in a patient's end-of-life decisions. This position was endorsed by Supreme Court Justice Stevens in his concurrence for both *Washington v. Glucksberg* and *Vacco v. Quill*, when he wrote:

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44. American Psychological Association Working Group, *supra* note 7; Cohen, *Suicide, Hastening Death, and Psychiatry*, 158 ARCH. INTERN. MED. 1973 (1998); Ganzini & Lee, *Psychiatry and Assisted Suicide in the United States*, 336 NEW ENG. J. MED. 1824 (1997); Werth & Holdwick, *A Primer on Rational Suicide and Other Forms of Hastened Death*, 28 COUNSELING PSYCHOLOGIST 511 (2000).

> I agree that the State has a compelling interest in preventing persons from committing suicide because of depression, or coercion by third parties. But the State's legitimate interest in preventing abuse does not apply to an individual who is not victimized by abuse, who is not suffering from depression, and who makes a rational and voluntary decision to seek assistance in dying. Although, as the New York Task Force report discusses, diagnosing depression and other mental illness is not always easy, mental health workers and other professionals expert in working with dying patients can help patients cope with depression and pain, and help patients assess their options.[45]

Thus, although the Coalition does not take a position here on either the general issue of "physician-assisted suicide" or the more particular issue of the legitimacy of prescribing controlled substances under the ODWDA, its members strongly believe the Court will gain substantial benefit by taking into account the substantial literature and experience set forth herein, as elsewhere, which demonstrates that the desire for death is not necessarily pathological. Moreover, the literature establishes that if there is impaired judgment or lack of capacity, these individuals or symptoms can be detected and interventions can be implemented.

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45. *Washington v. Glucksberg*, 521 U.S. at 735-36; *Vacco v. Quill*, 521 U.S. at 746-47.

CONCLUSION

The Coalition respectfully submits that the DOJ's reasoning for how the ODWDA's implementation leads to a threat to public health is flawed and misinformed. Many terminally ill patients are capable adults who are able to make a decision regarding use of the ODWDA free from impaired judgment, and adequate diagnostic tools are available for use in screening out those individuals who are not capable of making such a judgment.

Respectfully submitted,

STEVEN ALAN REISS
Counsel of Record
HARRIS J. YALE
SAMANTHA G. FISHERMAN
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, New York 10153
(212) 310-8000

Attorneys for Amicus Curiae Coalition of Mental Health Professionals

APPENDIX — COALITION MEMBERS

Individuals' affiliations are provided for identification purposes only. The views expressed are those of individual Coalition members and not necessarily those of any institution or organization with which they may be affiliated.

Sandra C. Anderson, Ph.D.
Professor
Graduate School of Social Work
Portland State University
Portland, Oregon

G. Andrew H. Benjamin, J.D., Ph.D.
Affiliate Professor of Law, University of Washington
Affiliate Professor of Psychology, Antioch University
Past President, Washington State Psychological Association
Advisory Board Member, American Psychological Association Ad Hoc Committee on End-of-Life Issues
Council Member, American Psychological Association
Seattle, Washington

Sarah Bradley, MSSW, LCSW
Licensed Clinical Social Worker
Faculty, Portland State University
Graduate School of Social Work
Portland, Oregon

Daniel Coleman, MSW, Ph.D.
Assistant Professor
Portland State University
Graduate School of Social Work
Portland Oregon

Appendix

M. Vicky East, Ph.D.
Licensed Psychologist, Private Practice
Member, Washington State Psychological Association
End-of-Life Task Force
Seattle, WA

Judith R. Gordon, Ph.D.
Licensed Psychologist, Private Practice
Clinical Professor of Psychology, University of Washington
Co-Chair, Washington State Psychological Association
End-of-Life Task Force
Advisory Board Member, American Psychological
Association Ad Hoc Committee on End-of-Life Issues
Seattle, Washington

Renee S. Katz, MSW, Ph.D.
Licensed Psychologist, Private Practice
Co-Chair, Washington State Psychological Association
End-of-Life Task Force
Chair, Ethics and Professional Standards Committee,
Association for Death Education and Counseling
Mercer Island, Washington

Elizabeth E. Landrum, Ph.D.,
Clinical Psychologist
Member, Washington State Psychological Association
End-of-Life Task Force
Edmonds, Washington

Appendix

David Lester, Ph.D.
Professor of Psychology, Richard Stockton College
Past President, International Association for
Suicide Prevention
Blackwood, New Jersey

E. James Lieberman, M.D., M.P.H.
Clinical Professor of Psychiatry
George Washington University School of Medicine
Washington, DC

Andrew McCormick, MSW
Licensed Independent Clinical Social Worker
Social Worker, Harborview Medical Center
Seattle, WA

Russell D. Miars, Ph.D.
Licensed Psychologist
Portland, Oregon

Paula B. Mike, ACSW, LCSW
Diplomate in Clinical Social Work
Assistant Professor
Portland State University
Graduate School of Social Work
Portland, Oregon

Pamela J. Miller, M.S.W., Ph.D.
Associate Professor
Portland State University
Graduate School of Social Work
Portland, Oregon

Appendix

Matthew J. Modrcin, Ph.D.
Licensed Clinical Social Worker
Lake Oswego, Oregon

Nico Peruzzi, Ph.D.
Partner, Outsource Research Consulting
Santa Clara, California

Paul A. Spiers, Ph.D.
Neuropsychology Associates, PC
Assistant Professor, Boston University School of Medicine.
Visiting Scientist, Massachusetts Institute of Technology
Boston, MA

James L. Werth, Jr., Ph.D.
Licensed Psychologist, Consultant – AIDS Holistic Services
Assistant Professor of Psychology, The University of Akron
Member, American Psychological Association Ad Hoc Committee on End-of-Life Issues
Akron, Ohio

Kathleen Worsley, PhD
Licensed Psychologist
Member, Washington State Psychological Association End-of-Life Task Force
Redmond, WA

Dr. Norman L. Wyers
Professor Emeritus, Portland State University
Graduate School of Social Work
Portland, Oregon

Appendix

Clinical Social Work Federation

National Association of Social Workers

Oregon Chapter, National Association of Social Workers

Oregon Psychological Association

Washington State Psychological Association

Supreme Court, U.S.
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No. 04-623

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

PAUL D. CLEMENT
Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

TABLE OF CONTENTS

	Page
I. The Attorney General reasonably concluded that assisting a person's suicide is not a "legitimate medical purpose" for which drugs can be distributed under the Controlled Substances Act	1
A. The Attorney General's interpretive rule is reasonable and is entitled to deference	1
B. The CSA establishes a uniform national standard for distributing controlled substances	6
II. There is no requirement of a clear statement applicable here	11
A. A presumption against federal preemption does not apply because the CSA does not preempt the DWDA	11
B. Because the CSA, as interpreted by the Attorney General, is clearly constitutional, the doctrine of constitutional avoidance does not apply	14
C. There is no requirement that Congress make a particularly "clear statement" whenever it addresses an issue that is also within "traditional state authority"	16

TABLE OF AUTHORITIES

Cases:

Alaska Dep't of Envtl. Conservation v. *EPA*, 540 U.S. 461 (2004)	4
Auer v. *Robbins*, 519 U.S. 452 (1997)	1, 2
Babbitt v. *Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687 (1995)	6
Barnhart v. *Walton*, 535 U.S. 212 (2002)	4

Cases—Continued: Page

California Div. of Labor Standards Enforcement v. *Dillingham Constr., N.A.*, 519 U.S. 316 (1997) 17
Caron v. *United States*, 514 U.S. 308 (1998) 13, 19
Chevron U.S.A. Inc. v. *NRDC*, 467 U.S. 837 (1984) 2, 3
Chicago & N.W. Transp. Co. v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981) 12
Christensen v. *Harris County*, 519 U.S. 576 (2000) 4
Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 13
City of Edmonds v. *Oxford House, Inc.*, 514 U.S. 725 (1995) 17
Department of Revenue v. *ACF Indus., Inc.*, 510 U.S. 332 (1994) 13
Dickerson v. *New Banner Inst., Inc.*, 460 U.S. 103 (1983) 13
Edward J. DeBartolo Corp. v. *Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568 (1988) 18
Elk Grove Unified Sch. Dist. v. *Newdow*, 124 S. Ct. 2301 (2004) 19
Gibbons v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824) 12
Gregory v. *Ashcroft*, 501 U.S. 452 (1991) 17
Gonzalez v. *Raich*, 125 S. Ct. 2195 (2004) 2, 3, 7, 8, 11, 14, 15, 16
Hillsborough County v. *Automated Med. Labs., Inc.*, 471 U.S. 707 (1985) 17
Hisquierdo v. *Hisquierdo*, 439 U.S. 572 (1979) 17
Hodel v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264 (1981) 17
Hyland v. *Fukuda*, 580 F.2d 977 (9th Cir. 1978) 12
Jerome v. *United States*, 318 U.S. 101 (1943) 19

Cases—Continued: Page

Jin Fuey Moy v. *United States*, 254 U.S. 189 (1920) 3
Jones v. *United States*, 529 U.S. 848 (2000) 13, 18
Kane v. *Kulongoski*, 871 P.2d 993 (Or. 1994) 12
Lambert v. *Yellowley*, 272 U.S. 581 (1926) 19
Linder v. *United States*, 268 U.S. 5 (1925) 19
Lottery Case, 188 U.S. 321 (1903) 15
Martin v. *OSHRC*, 499 U.S. 144 (1991) 2
Mississippi Bank of Choctaw Indians v. *Holyfield*, 490 U.S. 30 (1989) 18, 19
National Cable & Telecomm. Ass'n v. *Brand X Internet Servs.*, 125 S. Ct. 2688 (2005) 5
Raygor v. *Santa Fe Elevator Corp.*, 331 U.S. 218 (1947) 18
Robertson v. *Methow Valley Citizens Council*, 490 U.S. 332 (1989) 1
Rush Prudential HMO, Inc. v. *Moran*, 536 U.S. 355 (2002) 17
Shatz v. *United States Dep't of Justice*, 873 F.2d 1089 (8th Cir. 1989) 10
Solid Waste Agency v. *United States Army Corps. of Eng'rs*, 531 U.S. 159 (2001) 18
Thomas Jefferson Univ. v. *Shalala*, 512 U.S. 504 (1994) 1, 2
United States v. *Bass*, 404 U.S. 336 (1971) 13, 18
United States v. *Behrmann*, 258 U.S. 281 (1922) 3
United States v. *Darby*, 312 U.S. 100 (1941) 13, 15, 16, 18
United States v. *Lopez*, 514 U.S. 549 (1995) 18
United States v. *Mead Corp.*, 533 U.S. 213 (2001) 4
United States v. *Moore*, 423 U.S. 122 (1975) 2, 3, 8, 15
United States v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001) 3, 7

Cases—Continued: Page

Verizon Communications, Inc. v. *FCC*, 535 U.S. 467 (2002) 14
Webb v. *United States*, 249 U.S. 96 (1919) 3
Wickard v. *Filburn*, 317 U.S. 111 (1942) 16
Will v. *Michigan Dep't of State Police*, 491 U.S. 58 (1989) 18

Constitution, statutes and regulations:

U.S. Const.:
Art. IV, § 4 17
Amend. X 17
Administrative Procedure Act, 5 U.S.C. 553(b)(3)(A) 4
Fair Labor Standards Act of 1938, 29 U.S.C. 201 *et seq.* 13
Revenue Act of Feb. 24, 1919, § 1006, 40 Stat. 1131 2
PROTECT Act, Pub. L. No. 108-21, Tit. I, § 105(a), 117 Stat. 654 (to be codified at 18 U.S.C. 2423(b)) 16
18 U.S.C. 1073 16
18 U.S.C. 1958(a) 16
18 U.S.C. 2101(a)(1) 16
21 U.S.C. 801(1) 2, 7
21 U.S.C. 802(21) 7
21 U.S.C. 811(b) 4, 5
21 U.S.C. 811(c) 5
21 U.S.C. 811(c)(1) 5
21 U.S.C. 811(c)(4) 5
21 U.S.C. 811(c)(5) 5
21 U.S.C. 812(b)(1)-(5) 7
21 U.S.C. 812(b)(1)(B) 3
21 U.S.C. 812(b)(1)(C) 3
21 U.S.C. 823 11
21 U.S.C. 823(a)(1) 7
21 U.S.C. 823(f) 7, 9, 10, 11
21 U.S.C. 823(f) (1970) 9

Statutes and regulations—Continued: Page

21 U.S.C. 823(f)(4) 10
21 U.S.C. 823(f)(5) 10
21 U.S.C. 823(g)(1) 9
21 U.S.C. 824 11
21 U.S.C. 824(a) 10
21 U.S.C. 824(a)(2) (1970) 9
21 U.S.C. 830(b)(3)(A)(ii) 7
21 U.S.C. 903 12
Dealth with Dignity Act, Or. Rev. Stat. §§ 127.800 *et seq.* (2003) 3
21 C.F.R. 1306.04 ..... 7, 10
21 C.F.R. 1306.04(a) 1

Miscellaneous:

AMA, *Current Opinions of the Council of Ethical and Judicial Affairs, Opinion No. E-2.211, Physician-Assisted Suicide* (last visit Aug. 25, 2005) <http://www.ama-assn.org/ama/pub/category/print/8459.html> 19
36 Fed. Reg. 4948 (1971) 1
36 Fed. Reg. 7777 (1971) 1
36 Fed. Reg. 7799 (1971) 1
H.R. Rep. No. 1444, 91st Cong., 2d Sess. (1970) 3
S. Rep. No. 225, 98th Cong., 1st Sess. (1983) 10

I. THE ATTORNEY GENERAL REASONABLY CONCLUDED THAT ASSISTING A PERSON'S SUICIDE IS NOT A "LEGITIMATE MEDICAL PURPOSE" FOR WHICH DRUGS CAN BE DISTRIBUTED UNDER THE CONTROLLED SUBSTANCES ACT

A. The Attorney General's Interpretive Rule Is Reasonable And Is Entitled To Deference

1. Respondents challenge the Attorney General's regulatory interpretation that dispensing drugs for the purpose of hastening a person's death is not within "the usual course of professional treatment" or for a "legitimate medical purpose" within the meaning of the longstanding regulation that establishes the prerequisites for a lawful prescription under the Controlled Substances Act. See 21 C.F.R. 1306.04(a). The Attorney General's interpretation of his own regulation is "controlling unless 'plainly erroneous or inconsistent with the regulation.'" *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997) (quoting *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989)); *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994). That precondition for deference is amply satisfied here. The Attorney General's interpretation of the regulation is supported by the thrust of the Act it implements (which combats drug abuse, including overdoses), this Court's decisions under the Harrison Act and the CSA, the ordinary meaning of the terms "medical" and "medicine," centuries of tradition, federal law in other contexts, the position of 49 States, and the judgment of the American Medical Association that assisting suicide is "fundamentally incompatible" with a physician's role as healer. See Gov't Br. 21-24; p. 19, *infra*.

Patient-respondents suggest (at 9-12) that the Attorney General's interpretation is not entitled to deference under *Auer* because it was not issued after notice-and-comment rulemaking. That contention is mistaken. The underlying *regulation* the Attorney General interpreted *was* issued though notice and comment, 36 Fed. Reg. 4948, 7777, 7799

(1971), and respondents do not challenge the regulation's validity under *Chevron*. Nor could they because the regulation is firmly supported by the longstanding requirement—dating to the Harrison Act, which, as amended, excepted from its scope drugs obtained pursuant to "a prescription, written for legitimate medical uses," Revenue Act of Feb. 24, 1919, § 1006, 40 Stat. 1131, and reaffirmed in the CSA and *United States* v. *Moore*, 423 U.S. 122 (1975)—that a prescription must be for an accepted medical purpose in treatment, not for a non-medical purpose such as maintaining the habit of an addict. And there is no independent requirement that the interpretation of a notice-and-comment regulation also be the product of notice and comment. Such interpretations rarely follow notice and comment, and indeed *Auer* and its predecessors involved interpretations that were not the product of notice and comment. See *Auer*, 519 U.S. at 462; *Thomas Jefferson Univ.*, 512 U.S. at 510, 512; *Martin* v. *OSHRC*, 499 U.S. 144, 156-157 (1991). Accordingly, the regulation itself is concededly valid and the Attorney General's interpretation of it plainly qualifies for *Auer* deference. That is a sufficient basis to decide this case and reverse the decision below.

2. The Attorney General's rule is equally valid, however, even if respondents are somehow permitted to ignore the regulation and *Auer* and their suit is viewed as one challenging an interpretation of the Act itself. The interpretation embraced in the Attorney General's rule reflects an entirely reasonable construction of the Act, and therefore must be upheld under *Chevron*.

The CSA makes clear in its very first section that it permits the distribution of controlled substances only for "legitimate medical purposes"—those intended to "maintain the health and general welfare of the American people," 21 U.S.C. 801(1). The Act's clearly stated purpose is to enhance and maintain life, not to end it. This Court's decisions under the Harrison Act, which the CSA was intended to strengthen, *Gonzales* v. *Raich*, 125 S. Ct. 2195, 2202-2203 (2005),

made that central principle clear more than 80 years ago. See *Webb* v. *United States*, 249 U.S. 96, 99-100 (1919) (To call a doctor's order for morphine that was "not * * * issued * * * in the course of professional *treatment* in the attempted *cure* of the habit" "a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required.") (emphasis added); accord *Jin Fuey Moy* v. *United States*, 254 U.S. 189, 194 (1920); *United States* v. *Behrman*, 258 U.S. 280, 286, 288-289 (1922). And this Court followed the interpretation of those cases in *Moore*, 423 U.S. at 132, in a prosecution under the CSA.

Moreover, the CSA directs that substances be scheduled according to whether they have a "currently accepted medical use *in treatment*" and an "accepted *safety* for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(B) and (C) (emphasis added). There can be little doubt that a substance that had no utility in curing, treating, or alleviating disease, but was perfectly suited to causing a painless death, would be placed among the substances in schedule I as one having "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B). That scheduling decision would be made as a matter of federal law, and would bind physicians, even if state law were to the contrary. *Raich*, 125 S. Ct. at 2211-2213; *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 486, 492-493 (2001). While the schedule II substances prescribed under Oregon's Death with Dignity Act (DWDA), Or. Rev. Stat. §§ 127.800 *et seq.* (2003), do have some accepted medical uses, facilitating suicide is not one of them. A prescription issued for that purpose therefore is not for a legitimate medical purpose under the Act. The legislative history of the CSA confirms that using controlled substances to commit suicide is "misuse" under the CSA and a critical aspect of the pattern of abuse—including overdoses—that the Act was enacted to prevent. H.R. Rep. No. 1444, 91st Cong., 2d Sess. 35 (1970). This interpretation of the Act is eminently reasonable and therefore is controlling under *Chevron*.

3. That validity of the Attorney General's interpretation of the Act is unaffected by the fact that it was not issued after notice and comment. This Court has made clear that notice-and-comment rulemaking is not a prerequisite for *Chevron* deference. *Barnhart* v. *Walton*, 535 U.S. 212, 219-220, 221-222 (2002). And any such inflexible requirement would be contrary to the Administrative Procedure Act, the basic statutory framework for judicial review of agency action, which specifically exempts interpretive rules from the requirement of notice and comment. See 5 U.S.C. 553(b)(3)(A).

The patient-respondents' other objections to deference (at 10-28) are without merit. Respondents first object to the interpretation as "informal." See Patient Br. 11. But the interpretive rule was issued by the Attorney General himself, after considering the lengthy legal analysis of the Office of Legal Counsel, and his determination was published in the Federal Register. Pet. App. 100a-105a; *id.* at 106a-148a. No greater formality could be expected. This case therefore is a far cry from the cases the patient-respondents cite: *United States* v. *Mead Corp.*, 533 U.S. 218, 233 (2001) ("46 different * * * offices issue 10,000 to 15,000" rulings per year); *Alaska Department of Environmental Conservation*, 540 U.S. 461, 487 (2004) ("internal guidance memorandum"); *Christensen* v. *Harris County*, 529 U.S. 576, 587 (2000) (opinion letter).

The patient-respondents also contend (at 13-15) that the Attorney General's rule is not entitled to deference because he lacks medical expertise. They cite the role assigned to the Secretary of Health and Human Services in the CSA with respect to the scheduling of controlled substances. *Id.* at 15 (citing 21 U.S.C. 811(b)). But as the practitioner-respondents realize (at 20-33), this case does not implicate the authority to schedule controlled substances, which may touch upon technical scientific and medical matters. Rather, it presents a legal question for the Attorney General to resolve by interpreting one of his own regulations and the

provisions of the CSA it implements. Nor is there anything anomalous about a scheme that requires broader input on the ultimate question of scheduling a drug than on a decision that particular practices are abusive or illegitimate. In cases such as *Webb* and *Moore*, the Court sustained criminal prosecutions initiated by the Department of Justice based on the Department's judgment that the prescriptions were improper, with no suggestion that prior approval by some other federal agency was required.

Even as to scheduling, respondents overstate the role of the Secretary. His views are binding on the Attorney General only as to "such scientific and medical matters" as are specifically referred to the Secretary in the scheduling process. See 21 U.S.C. 811(b) and (c). The statute makes clear that the Secretary's comments about a substance's "potential for abuse," "pattern of abuse," or "significance of abuse," 21 U.S.C. 811(b), (c)(1), (4) and (5), are binding on the Attorney General *only* as to any "scientific and medical considerations," 21 U.S.C. 811(b). Congress thus recognized that even in the scheduling process, determinations about a substance's "abuse" may not be scientific or medical in nature, but might instead involve legal or other considerations that are for the Attorney General to resolve.

Respondents also emphasize that the interpretive rule at issue here is contrary to the views of the preceding Attorney General. Patient Br. 16, 21-22, 27-28. This Court's recent decision in *National Cable & Telecommunications Ass'n* v. *Brand X Internet Services*, 125 S. Ct. 2688 (2005), provides a complete legal answer to that argument. "Agency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework." *Id.* at 2699. In addition, the position of the Attorney General that respondents challenge, unlike the views of his predecessor set forth in a letter to Members of Congress, took the form of agency action, after a thorough legal analysis, published in the Federal Register.

Finally, respondents object (Patient Br. 16-19, 20-21, 30-35) that the thorough analysis on which the Attorney General's decision was based did not discuss Oregon's experience under the DWDA or other views supportive of assisted suicide as a policy matter. But, because that analysis focused on what constitutes a "legitimate medical purpose" as a *legal* matter and on the judgment that suicide, including physician-assisted suicide, is *itself* harmful to public health and safety, Oregon's data concerning the experience of persons who receive drugs and commit suicide as permitted by the DWDA were irrelevant. The patient-respondents' other evidence consists of a few opinion polls, the support of specialized professional groups and associations, and recent legal developments in a few foreign countries. Patient Br. 30-35. Even respondents concede that, at most, that evidence indicates that public opinion is "divided" on this issue, Patient Br. 30.[1]

B. The CSA Establishes A Uniform National Standard For Distributing Controlled Substances

Apart from their challenge to the Attorney General's interpretation on deference grounds, respondents offer three statutory arguments why the CSA should be construed to take the determination out of federal hands altogether and make state law the arbiter of whether distribution of a drug is for a "legitimate medical purpose" under the CSA. None is persuasive.

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[1] Certain of respondents' amici, but not respondents, argue that the Attorney General's interpretive ruling should be rejected because of the "rule of lenity." Briffault Br. 19-22. In *Babbitt* v. *Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687 (1995), the Court rejected the suggestion "that the rule of lenity should provide the standard for reviewing facial challenges to administrative regulations whenever the governing statute authorizes criminal enforcement." *Id.* at 704 n.18. There is no question that the Attorney General's interpretive rule gives "[a]dequate notice of potential liability" to practitioners if they use their federal registration to assist someone to commit suicide. *Ibid.* The rule of lenity is therefore inapplicable.

1. Practitioner-respondents argue (at 13-14, 23) that it is the statutory phrase "in the course of professional practice," 21 U.S.C. 802(21), rather than the regulatory phrase "legitimate medical purpose," 21 C.F.R. 1306.04, that governs, and that the former necessarily incorporates medical practice under state law. That argument simply ignores the fact that the CSA itself uses the term "legitimate" to modify "medical purpose" or medical "use" in at least four different provisions, including the Act's very first declaration of congressional purpose, 21 U.S.C. 801(1). See also 21 U.S.C. 830(b)(3)(A)(ii) (defining "valid prescription" as one "issued for a legitimate medical purpose"), 823(a)(1), 823(f). It also ignores the absence of any language even in "the course of professional practice" phrase that ties it to practice in a particular state or locality.

More broadly, the practitioners fail to grasp that the CSA does not merely regulate the conduct of doctors in particular localities; it imposes affirmative nationwide duties on the Attorney General to act based upon his determination whether an asserted medical purpose is "legitimate" or "accepted." For example, the Attorney General must schedule substances according to whether they have a "currently accepted medical use in treatment *in the United States*," 21 U.S.C. 812(b)(1)-(5) (emphasis added), and must regulate the manufacture of controlled substances to ensure "an adequate and uninterrupted supply" for "legitimate medical, scientific, research and industrial purposes," 21 U.S.C. 823(a)(1). It is untenable, especially in light of this Court's recent decision in *Raich* upholding the CSA's blanket prohibition on marijuana use despite California's recognition of its medicinal utility, to maintain that the Attorney General is constrained to adopt a particular State's policy regarding what is an "accepted" or "legitimate" medical purpose or use. 125 S. Ct. at 2211; *Oakland Cannabis*, 532 U.S. at 486, 492-493. The Attorney General would not need to remove a drug from schedule I because one State recognized an idiosyncratic use for an otherwise banned substance. There is no more reason

for the Attorney General to have to treat a prescription that would be unlawful and improper as a matter of federal law in 49 States as legitimate because of the idiosyncratic view of a single State. That would be true of a State that purported to allow prescriptions of the sort at issue in *Moore*, and is no less true of a State that allows prescriptions for a use (facilitating a lethal overdose) that amounts to abuse in 49 States and as a matter of federal law.

2. Alternatively, the practitioner-respondents argue (at 25) that Congress was concerned only with doctors "diverting drugs outside of legitimate channels." To the extent respondents mean that Congress was *not* concerned with the purposes for which a doctor prescribes medicine to a patient, except to the extent the patient might *resell* the drugs outside "legitimate channels," that contention is simply wrong. As the Court recognized in *Raich*, "the CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, *and in what manner*," 125 S. Ct. at 2211 (emphasis added). See *Moore*, 423 U.S. at 143 (CSA establishes "limits on free experimentation with drugs" by physicians). Indeed, diversion from legitimate uses to illegitimate uses via otherwise legitimate channels (*e.g.*, prescriptions from a doctor to a patient) was a primary concern of the Harrison Act prosecutions and *Moore*. Similarly in this case, the diversion of schedule II substances from legitimate uses as medicine to what in every other State and under federal law amounts to abuse and the facilitation of a lethal overdose *is diversion* for purposes of the CSA.[2]

[2] Moreover, Oregon's representation (at 23 n.9) that prescriptions under DWDA pose no risk of diversion to others is not borne out. A lethal dose under DWDA is approximately 90 to 100 times the therapeutic dose. Oregon Br. 43. And it appears that a high percentage of persons for whom a lethal dose is prescribed do not end up taking the prescribed drugs, Patient Br. 39, thus leaving a large quantity of strictly regulated schedule II substances unaccounted for and outside the CSA's closed system.

After criminal prosecutions such as *Moore* confirmed the basic legal distinction under the CSA between legitimate medical *treatment* of addicts and illicit dispensing of drugs to maintain an addict's habit, the Act was amended to provide for the Secretary to articulate more specific criteria for when a physician can prescribe narcotic drugs to patients for "maintenance treatment or detoxification treatment." 21 U.S.C. 823(g)(1); see Gov't Br. 33-34. But that mechanism for fleshing out the established *legal* standard in a particular context simply confirms that the CSA itself more generally embodies a basic federal statutory limitation on what constitutes a "legitimate medical purpose." If prescribing controlled substances to sustain addiction during life is not such a purpose, then *a fortiori* prescribing drugs to cause death crosses the statutory line. No medical or scientific expertise of the Secretary is required for the Attorney General to resolve that basic question of statutory interpretation.

3. Respondents contend that the CSA's reference to state licensing decisions in 21 U.S.C. 823(f) indicates a congressional intent that state, rather than federal, law provide the sole reference point for determining whether a particular physician's dispensing of drugs is permissible under the CSA. Practitioner Br. 29-33; Oregon Br. 35-38. Section 823(f) governs the granting of federal registration to dispense controlled substances, not the conduct of physicians after they are registered. Gov't Br. 34-35. Nonetheless, its history is instructive. When the CSA was adopted, Congress piggybacked on state licensing boards to determine who would obtain a federal registration in the first instance. See 21 U.S.C. 823(f) (1970). But even then the State's licensing decision was not dispositive with respect to federal registration, because registration could be revoked if the registrant was convicted of a felony under the CSA or any other law of the United States (or of any State) relating to a controlled substance. 21 U.S.C. 824(a)(2) (1970). Neither Section 823(f) nor any other provision of the CSA was ever understood to require that the federal government await a

determination by a state licensing board before prosecuting a doctor under the CSA or revoking the federal registration based on a conviction. Gov't Br. 31-33.

Significantly, moreover, Congress amended the Act in 1984 to allow the Attorney General to deny, suspend, or revoke a practitioner's registration on other *federal* grounds as well. See 21 U.S.C. 823(f), 824(a). Now, the Attorney General must also consider "[t]he applicant's experience in dispensing * * * controlled substances," "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," and "[s]uch other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(2), (4), and (5).

Congress revised the earlier provisions in part because States were not adequately regulating physicians' abuses of their prescription-writing authority. See S. Rep. No. 225, 98th Cong., 1st Sess. 262 (1983) (noting that it "may clearly be contrary to the public interest" to require federal registration of any practitioner licensed under state law); *id.* at 266. Thus, the 1984 amendments granted the Attorney General considerably *broader* authority to take administrative action on independent federal grounds. It is also clear that the references to violations of federal, state, *or* local law are in the disjunctive and that any one of the enumerated factors in Section 823(f) can be dispositive. See, *e.g.*, *Shatz* v. *United States Dep't of Justice*, 873 F.2d 1089 (8th Cir. 1989). It is clear, for example, that the Attorney General may now revoke the registration of a physician who engages in improper prescription practices of the sort involved in *Moore*, without waiting for a federal criminal conviction much less a state-law conviction or action by state registration authorities.

The patient-respondents suggest (at 42-44) that the Attorney General's interpretive rule violates Section 823(f) because it gives insufficient weight to Oregon law. The Attorney General's rule is not, however, an application of the registration provisions in Section 823(f), but an interpretation of the *substantive* federal law requirements (under 21 C.F.R. 1306.04) for a valid prescription. Because compliance with

federal law, *viz* the CSA (including the prescription requirement), is itself a consideration in registration decisions under Section 823(f), the interpretive rule puts registrants on notice of an important determination of the Attorney General regarding federal law that *could* affect their registrations. In short, Sections 823 and 824 make clear that a doctor can lose his or her federal license by violating state law, local law *or* federal law. A doctor might lose federal registration based on violations of state laws that have no federal analog because the state-law violation may demonstrate indirectly that a doctor is unfit for federal-law purposes. A violation of federal law demonstrates unfitness more directly and can occur even if state law does not regulate or criminalize the conduct.

II. THERE IS NO REQUIREMENT OF A CLEAR STATEMENT APPLICABLE HERE

For the reasons stated above, the Attorney General's ruling is clearly sound under normal rules of statutory construction. Respondents urge, however, that the usual principles do not apply here. Rather, they contend that the CSA can restrict conduct that state law would permit only if the statute contains a "clear statement" to that effect. This Court has already recognized that the CSA reflects a comprehensive regime that does not need to yield just because a State has chosen to remove state-law prohibitions on certain conduct independently prohibited by federal law. *Raich*, 125 S. Ct. at 2203. And respondents cannot point to any authority requiring federal authorities to identify a "clear statement" of legislative intent before applying a comprehensive scheme to such conduct.

A. A Presumption Against Federal Preemption Does Not Apply Because The CSA Does Not Preempt The DWDA

Oregon contends that a "presumption against preemption" applies—and a "clear statement" is required—whenever a federal regulation would "prevent" a more permissive "state

law from operating as state lawmakers intended." Oregon Br. 20-21. That argument is flatly wrong and, if accepted, would dramatically alter the relationship between state and federal law.

Respondents' reliance on the presumption against preemption suffers a singular flaw: This is not a preemption case. Preemption refers to those circumstances in which "the Supremacy Clause invalidates state laws that 'interfere with or are contrary to the laws of Congress.'" *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824)). The combined effect of federal law and the Supremacy Clause renders such state statutes unconstitutional. The CSA does not preempt Oregon law. The CSA prohibits physicians from prescribing federally-controlled substances for the purpose of assisting a person to commit suicide. The DWDA removes pre-existing state-law sanctions on facilitating suicide in certain circumstances. See *Kane* v. *Kulongoski*, 871 P.2d 993, 998 (Or. 1994). Nothing in the CSA invalidates the DWDA or prevents the use of means other than federally-controlled substances for the commission of suicide.

When "Congress has chosen to prohibit an act which [the State] has chosen not to prohibit; there is no conflict," *Hyland* v. *Fukuda*, 580 F.2d 977, 981 (9th Cir. 1978), and any presumption against preemption is therefore inapposite. Respondents' reliance (Oregon Br. 26-27; Practitioner Br. 45-46) on the CSA's preemption clause, 21 U.S.C. 903, is thus misplaced. That provision clarifies Congress's intent not to preempt the entire *field* of controlled substances. But, since the Attorney General's interpretive ruling does not "preempt" Oregon law in any way, let alone the field, Section 903 is simply irrelevant.

What Oregon actually proposes (Br. 20-21), then, is a radical new presumption that would effectively invert the Supremacy Clause and, in the absence of a clear statement, bar federal regulation whenever it would "frustrat[e]" a State's

choice to permit conduct that federal law prohibits. That proposition has no support in the cases Oregon cites,[3] and would either completely invert the constitutional relationship between the federal and state governments or at a minimum resurrect the cramped notions of federal power that the Court definitively rejected in *United States* v. *Darby*, 312 U.S. 100 (1941). In *Darby*, the respondent challenged the Fair Labor Standards Act of 1938, 29 U.S.C. 201 *et seq.*, on the ground that it "undertakes to regulate wages and hours within the state contrary to the policy of the state which has elected to leave them unregulated." 312 U.S. at 114. The Court rejected that contention, ruling that Congress is "free to exclude from commerce" conduct that "it may conceive to be injurious to the public health, morals or welfare, even though the state has not sought to regulate their use." *Ibid.*

Although *Darby* concerned Congress's constitutional authority, other cases reject the same proposition as a matter of statutory construction. For example, in *Caron* v. *United States*, 524 U.S. 308 (1998), the Court interpreted a federal statute to prohibit an individual from possessing rifles and shotguns, *id.* at 316-317, even though the State specifically allowed such possession, *id.* at 311. Similarly, in *Dickerson* v. *New Banner Institute Inc.*, 460 U.S. 103 (1983), the Court held that, for purposes of federal gun laws, the determinations whether an individual had been "convicted" in state court and whether that conviction had later been nullified were "question[s] of federal, not state, law," *id.* at 111-112, even though the respondent's gun rights might have been restored as a matter of state law, *id.* at 114 n.9.

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[3] Two of those cases, *Jones* v. *United States*, 529 U.S. 848 (2000), and *United States* v. *Bass*, 404 U.S. 336 (1971), involved the doctrine of constitutional avoidance, which we address below. See pp. 14-16, *infra*. The other two involved classic questions of preemption. See *Department of Revenue* v. *ACF Indus., Inc.*, 510 U.S. 332, 335-336 (1994); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 508 (1992).

B. Because The CSA, As Interpreted By The Attorney General, Is Clearly Constitutional, The Doctrine Of Constitutional Avoidance Does Not Apply

Respondents invoke the doctrine of constitutional avoidance, under which courts prefer an interpretation of an ambiguous statute that avoids "a serious constitutional question." *Verizon Communications, Inc.* v. *FCC*, 535 U.S. 467, 523 (2002). Oregon Br. 42; see Patient Br. 23; Practitioner Br. 47-50. As explained above, however, the CSA is not ambiguous. Nor is its constitutionality, as interpreted by the Attorney General, doubtful.

Respondents' contention that Congress lacks authority under the Commerce Clause to regulate the distribution of schedule II controlled substances in Oregon is foreclosed, *a fortiori*, by this Court's decision in *Raich*, which rejected a Commerce Clause challenge to Congress's authority to regulate even the home cultivation and consumption of marijuana, including marijuana that is to be used for purported medicinal purposes on the basis of a physician's recommendation as authorized by state law. 125 S. Ct. at 2207. The class of conduct at issue in *Raich* was "purely intrastate activity that is not itself 'commercial,' in that it is not produced for sale." *Id.* at 2206. Here, by contrast, the CSA directly regulates the commerce between physician and patient or pharmacist and customer in schedule II controlled substances that, by Oregon's own admission (Br. 43 & n.18), are produced commercially and have, in all likelihood, "traveled in interstate commerce."

Respondents assert that the Attorney General's interpretive rule is nonetheless unconstitutional because there is no evidence that controlled substances prescribed under the DWDA "have or will enter into the stream of *illicit* commerce." Practitioner Br. 49 (emphasis added). But that argument is both circular and unpersuasive. The prescription of drugs for the purpose of enabling a person to take his own life is "illicit" *under the CSA*, and its legality and consequent regulation (to an extent) under Oregon law does not diminish

federal authority. *Raich*, 125 S. Ct. at 2213 n.38; *id.* at 2219-2220 (Scalia, J., concurring in the judgment). Nor, in any event, is Congress's Commerce Clause authority limited by the licit or illicit nature of the activity regulated. The CSA is equally constitutional in its prohibition of schedule I substances and its regulation of sometimes lawful schedule II substances. Oregon also errs in suggesting that because a relatively small number of individuals can avail themselves of the DWDA, the total amount of drugs at issue is too "insignificant" for Congress to regulate. Oregon Br. 45. "[W]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power to excise, as trivial, individual instances of the class." *Raich*, 125 S. Ct. at 2209 (quotation marks omitted). It is the class of activities that Congress has forbidden—not the class of activities that state law decriminalizes—that must have the requisite impact on interstate commerce, and that standard is satisfied here, just as it was in *Raich*. *Id.* at 2208.

Oregon contends that Congress's power under the Commerce Clause is limited to regulating the "commercial aspects" of a transaction, and that it cannot make the application of federal law turn on "a physician's or patient's intentions about the ultimate use of the drugs" at issue. Oregon Br. 43-44. However, the Court made clear long ago that Congress's Commerce Clause power is not limited to some narrow category of concerns about the "commercial aspects" of transactions, but may be exercised, based on Congress's "own conception of public policy," to prohibit what it "may conceive to be injurious to the public health, morals or welfare." *Darby*, 312 U.S. at 114; see also *The Lottery Case*, 188 U.S. 321, 354 (1903). There is nothing unusual, let alone constitutionally suspect, about federal laws that regulate conduct based on the actor's purpose or intent. In *Moore*, for example, the Court upheld a physician's conviction under the CSA precisely because he had prescribed methadone to feed his patients' habits, rather than for "detoxification purposes," the only purpose allowed under the Act. 423 U.S. at

144-145.[4] Nor does the fact that a physician acts "pursuant to affirmative state law," Oregon Br. 47, shield his activity from Congress's constitutional reach, for "state action cannot circumscribe Congress' plenary commerce power." *Raich*, 125 S. Ct. at 2213; *Wickard* v. *Filburn*, 317 U.S. 111, 124 (1942); *Darby*, 312 U.S. at 114. Indeed, the logic of respondents' Commerce Clause argument is that the federal government lacks the authority to revoke a doctor's license for prescribing controlled substances for purposes of assisting suicide not just in Oregon, but in the 49 States that prohibit the conduct.

C. There Is No Requirement That Congress Make A Particularly "Clear Statement" Whenever It Addresses An Issue That Is Also Within "Traditional State Authority"

Respondents finally suggest that a clear statement is necessary because the CSA, as interpreted by the Attorney General, "would intrude upon the historic powers of the States" and "alter the usual state-federal balance." Oregon Br. 28, 30 (quotation marks omitted). See Practitioner Br. 47-50; Patient Br. 23-24. That proposition is singularly inapposite here: the federal government has regulated the distribution of controlled substances for 90 years, *Raich*, 125 S. Ct. at 2202, whereas, prior to 1994, no State had ever purported to allow physicians to dispense controlled substances for the purpose of assisting a person's suicide.

More broadly, Oregon asserts (Br. 34 & n.15) that a "clear statement" is required whenever federal regulation would have an impact on "States' regulation of the health, welfare, and comfort of their citizens." But that category of state authority encompasses everything not forbidden by the Constitution. See *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 311 (1981). Respondents' broad anti-federal-regulation presumption therefore would mark a sea-change in the Court's jurisprudence. None of the cases cited by respondents (Oregon Br. 27-34, 38-42) support such a sweeping rule.

Oregon primarily relies (Br. 31-34) on *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), but *Gregory* stands for no such proposition. The question presented was one of federal *preemption* of state law—whether the federal Age Discrimination in Employment Act prohibited Missouri from enforcing a state constitutional requirement that judges retire at seventy. See *id.* at 455, 460. Moreover, because the state law at issue concerned "[t]he authority of the people of the States to determine the qualifications of their government officials," preemption by federal law would have encroached upon "how a State defines itself as a sovereign" and presented a "potential constitutional problem," under the Guarantee Clause, U.S. Const., Art. IV, § 4, and the Tenth Amendment. *Gregory*, 501 U.S. at 460, 463-464; see *City of Edmonds* v. *Oxford House, Inc.*, 514 U.S. 725, 732 n.5 (1995) (emphasizing that Missouri's interest in setting the qualifications of judicial office went "*beyond* an area traditionally regulated by the States," to the core of state sovereignty) (quoting *Gregory*, 501 U.S. at 460) (emphasis added). This case implicates neither basis for triggering a clear-statement requirement.

Oregon contends (Br. 31-34) that, even if *Gregory* is not directly applicable, other decisions have applied *Gregory*'s clear statement requirement more broadly. But the other cases Oregon cites are likewise inapposite. Most are yet further examples of the presumption against preemption of state law in particular contexts.[5] Others are instances of the

[4] Similarly, federal law prohibits interstate travel only when done with specified intent, such as "for the purpose of engaging in any illicit sexual conduct with another person," PROTECT Act, Pub. L. 108-21, Title I, § 105(a), 117 Stat. 654 (to be codified at 18 U.S.C. 2423(b)), with intent to commit murder for hire, 18 U.S.C. 1958(a), with intent to avoid prosecution, 18 U.S.C. 1073, and with intent to incite a riot, 18 U.S.C. 2101(a)(1).

[5] See, *e.g.*, *Rush Prudential HMO, Inc.* v. *Moran*, 536 U.S. 355, 359 (2002); *California Div. of Labor Standards Enforcement* v. *Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 319 (1997); *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 714-715 (1985); *Hisquierdo* v.

doctrine of constitutional avoidance.[6] And two involved the presumption that Congress does not intend to abrogate the States' sovereign immunity—a core aspect of state sovereignty.[7] None of those canons of construction is implicated by the application of the CSA to commercial transactions in controlled substances among physicians, pharmacists, and their customers, even if, as in *Raich*, the CSA prohibits transactions that state law would allow.

Respondents' inability to cite examples of the Court's applying a clear-statement rule merely because federal law regulates private conduct in a manner more restrictive than state law is not surprising. Giving effect to more stringent federal law does not "alter the usual state-federal balance," Oregon Br. 30. Rather, that *is* the usual state-federal balance under the Constitution, which permits Congress to legislate according to "its own conception of public policy." *Darby*, 312 U.S. at 114. Thus, as we discussed in our opening brief, the "general assumption" is that the terms of a federal statute do not depend upon state law but instead should be given "uniform nationwide application." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989).

The Court has, moreover, applied the presumption of federal uniformity to statutes that legislate in areas within "traditional state regulatory powers," Oregon Br. 28. In *Mississippi Band* itself, the Court held that a uniform federal definition should be given to the ambiguous term "domicile" in the Indian Child Welfare Act, even though the subject matter—family law, specifically child custody—is near the epicenter of conduct traditionally regulated by the States. See *Elk Grove Unified School Dist.* v. *Newdow*, 124 S. Ct. 2301, 2309 (2004).[8] Likewise, in *Caron* the Court gave a uniform federal meaning to the gun statute in light of the federal government's "interest in a single, national, protective policy, broader than required by state law." 524 U.S. at 316.

Respondents cite numerous cases that comment on the States' historic role in regulating medicine (Practitioner Br. 44; Oregon Br. 47 & n.22; Patient Br. 24 n.11), but none—apart from long-ago-overruled language in *Linder* v. *United States*, 268 U.S. 5 (1925), see Gov't Br. 40-41—suggests that a federal law concerning medicine is somehow more suspect than statutes in other areas like family law or gun possession that States have also traditionally regulated. And the Court's decisions in *Raich* and *Oakland Cannabis* positively refute that proposition specifically with respect to the CSA. See also *Lambert* v. *Yellowley*, 272 U.S. 581, 596 (1926) ("[T]here is no right to practice medicine which is not subordinate to * * * the power of Congress to make laws necessary and proper" to its constitutional authority.).

Although respondents refer repeatedly to the tradition of state regulation of medicine, the DWDA and its approach to assisted suicide does not resemble any traditional regulation of "medicine." Assisting in a person's suicide is, as the American Medical Association ethics guidelines recognize, "fundamentally incompatible with the physician's role as healer." AMA, *Current Opinions of the Council of Ethical*

Hisquierdo, 439 U.S. 572, 581, 590 (1979); *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 236 (1947).

[6] See, *e.g.*, *Raygor* v. *Regents of the Univ. of Minn.*, 534 U.S. 533, 543-544 (2002); *Solid Waste Agency* v. *United States Army Corps of Eng'rs*, 531 U.S. 159, 172-173 (2001); *Jones* v. *United States*, 529 U.S. 848, 857-858 (2000); *Edward J. DeBartolo Corp.* v. *Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); *United States* v. *Bass*, 404 U.S. 336, 339 n.4 (1971). See also *United States* v. *Lopez*, 514 U.S. 549, 562 (1995) (characterizing *Bass* as an example of constitutional avoidance).

[7] See *Raygor*, 534 U.S. at 543; *Will* v. *Michigan Dep't of State Police*, 491 U.S. 58 (1989).

[8] Oregon characterizes (at 16 n.7) *Mississippi Band* as involving a "clearly demonstrated [congressional] intent to displace state court jurisdiction." But that is not how the Court described its own reasoning. Rather, the opinion states that "[w]e *start* * * * with the *general* assumption that 'in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent upon state law.'" 490 U.S. at 43 (emphasis added) (quoting *Jerome* v. *United States*, 318 U.S. 101, 104 (1943)).

and Judicial Affairs, Opinion No. E-2.211, Physician-Assisted Suicide, (last visited Aug. 25, 2005) <http://www.ama-assn.org/ama/pub/category/print/ 8459.html>. Moreover, the DWDA regulates assisted suicide differently from Oregon's own regulation of medicine. The DWDA's allowance of prescriptions for assisted suicide, while prohibiting physicians from actually administering the lethal drugs (see Oregon Br. 2, Practitioner Br. 15), which presumably reflects Oregon's own apparent discomfort with the idea of physicians directly causing death, is unique. Respondents point to no other circumstance, and we are aware of none, in which a doctor "may prescribe, but not administer," a substance. Oregon Br. 2. That simply does not happen when the controlled substance is being dispensed as "medicine." Moreover, that anomaly only underscores that the DWDA relies not on the physician's medical knowledge (the lethal substances and the required dosages have been well publicized in Oregon's DWDA reports, see Oregon Br. 43 & n.20.), but on the physician's federal-law status as a distributor of schedule II substances. The Attorney General's interpretation thus represents not an effort to reverse a state-law judgment about assisted suicide (which remains valid in Oregon to the extent is does not involve federally-controlled substances), but an effort to prevent a State from commandeering a federal-licensee's ability to dispense schedule II substances for ends that are contrary to federal law and bear little resemblance to traditional medicine.

* * * * *

For the foregoing reasons and those stated in the opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

PAUL D. CLEMENT
Solicitor General

AUGUST 2005

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

GONZALES, ATTORNEY GENERAL, ET AL. *v.* OREGON ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 04–623. Argued October 5, 2005—Decided January 17, 2006

The Controlled Substances Act (CSA or Act), which was enacted in 1970 with the main objectives of combating drug abuse and controlling legitimate and illegitimate traffic in controlled substances, criminalizes, *inter alia*, the unauthorized distribution and dispensation of substances classified in any of its five schedules. The Attorney General may add, remove, or reschedule substances only after making particular findings, and on scientific and medical matters, he must accept the findings of the Secretary of Health and Human Services (Secretary). These proceedings must be on the record after an opportunity for comment. The dispute here involves controlled substances listed in Schedule II, which are generally available only by written prescription, 21 U. S. C. §829(a). A 1971 regulation promulgated by the Attorney General requires that such prescriptions be used "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR §1306.04. To prevent diversion of controlled substances, the CSA regulates the activity of physicians, who must register in accordance with rules and regulations promulgated by the Attorney General. He may deny, suspend, or revoke a registration that, as relevant here, would be "inconsistent with the public interest." 21 U. S. C. §§821(a)(4), 822(a)(2). In determining consistency with the public interest, he must consider five factors, including the State's recommendation, compliance with state, federal, and local law regarding controlled substances, and "public health and safety." §823(f). The CSA explicitly contemplates a role for the States in regulating controlled substances. See §903.

The Oregon Death With Dignity Act (ODWDA) exempts from civil

Syllabus

or criminal liability state-licensed physicians who, in compliance with ODWDA's specific safeguards, dispense or prescribe a lethal dose of drugs upon the request of a terminally ill patient. In 2001, the Attorney General issued an Interpretive Rule to address the implementation and enforcement of the CSA with respect to ODWDA, declaring that using controlled substances to assist suicide is not a legitimate medical practice and that dispensing or prescribing them for this purpose is unlawful under the CSA. The State, a physician, a pharmacist, and some terminally ill state residents challenged the Rule. The District Court permanently enjoined its enforcement. The Ninth Circuit invalidated the Rule, reasoning that, by making a medical procedure authorized under Oregon law a federal offense, it altered the balance between the States and the Federal Government without the requisite clear statement that the CSA authorized the action; and in the alternative, that the Rule could not be squared with the CSA's plain language, which targets only conventional drug abuse and excludes the Attorney General from medical policy decisions.

Held: The CSA does not allow the Attorney General to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide under state law permitting the procedure. Pp. 8–28.

(a) An administrative rule interpreting the issuing agency's own ambiguous regulation may receive substantial deference. *Auer* v. *Robbins*, 519 U. S. 452, 461–463. So may an interpretation of an ambiguous statute, *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–845, but only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority," *United States* v. *Mead Corp.*, 533 U. S. 218, 226–227. Otherwise, the interpretation is "entitled to respect" only to the extent it has the "power to persuade." *Skidmore* v. *Swift & Co.*, 323 U. S. 134, 140. Pp. 8–9.

(b) The Interpretive Rule at issue is not entitled to *Auer* deference as an interpretation of 21 CFR §1306.04. Unlike the underlying regulations in *Auer*, which gave specificity to a statutory scheme the Secretary of Labor was charged with enforcing and reflected the Labor Department's considerable experience and expertise, the underlying regulation here does little more than restate the terms of the statute itself. The CSA allows prescription of drugs that have a "currently accepted medical use," 21 U. S. C. §812(b); requires a "medical purpose" for dispensing the least controlled substances of those on the schedules, §829(c); and defines a "valid prescription" as one "issued for a legitimate medical purpose," 21 U. S. C. A. §830(b)(3)(A)(ii). Similarly, physicians are considered practitioners if

Syllabus

they dispense controlled substances "in the course of professional practice." 21 U. S. C. §802(21). The regulation just repeats two of these statutory phrases and attempts to summarize the others. An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language. Furthermore, any statutory authority for the Interpretive Rule would have to come from 1984 CSA amendments adding the "public interest" requirement, but 21 CFR §1306.04 was adopted in 1971. That the current interpretation runs counter to the intent at the time of the regulation's promulgation is an additional reason why *Auer* deference is unwarranted. Pp. 9–11.

(c) The Interpretive Rule is also not entitled to *Chevron* deference. The statutory phrase "legitimate medical purpose" is ambiguous in the relevant sense. However, *Chevron* deference is not accorded merely because the statute is ambiguous and an administrative official is involved. A rule must be promulgated pursuant to authority Congress has delegated to the official. The specific respects in which the Attorney General is authorized to make rules under the CSA show that he is not authorized to make a rule declaring illegitimate a medical standard for patient care and treatment specifically authorized under state law. Congress delegated to the Attorney General only the authority to promulgate rules relating to "registration" and "control" of the dispensing of controlled substances, 21 U. S. C. A. §821, and "for the efficient execution of his [statutory] functions," 21 U. S. C. §871(b). Control means "to add a . . . substance to a schedule," §802(5), following specified procedures. Because the Interpretive Rule does not concern scheduling of substances and was not issued under the required procedures, it cannot fall under the Attorney General's control authority. Even if "control" were understood to signify something other than its statutory definition, it could not support the Interpretive Rule. Nor can the Interpretive Rule be justified under the CSA's registration provisions. It does not undertake the Act's five-factor analysis for determining when registration is "inconsistent with the public interest," §823(f), and it deals with much more than registration. It purports to declare that using controlled substances for physician-assisted suicide is a crime, an authority going well beyond the Attorney General's statutory power to register or deregister physicians. It would be anomalous for Congress to have painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside the course of professional practice, and therefore a criminal violation of the CSA. It is not enough that "public interest,"

"public health and safety," and "Federal law" are used in the part of the Act over which the Attorney General has authority. Cf. *Sutton* v. *United Air Lines, Inc.*, 527 U. S. 471. The first two terms do not call on the Attorney General, or any Executive official, to make an independent assessment of the meaning of federal law. The Attorney General did not base the Interpretive Rule on an application of the five-factor test generally, or the "public health and safety" factor specifically. Even if he had, it is doubtful that he could cite those factors to deregister a physician simply because he deemed a controversial practice permitted by state law to have an illegitimate medical purpose. The federal-law factor requires the Attorney General to decide "[c]ompliance" with the law but does not suggest that he may decide what the law is. To say that he can define the substantive standards of medical practice as part of his authority would also put 21 U. S. C. §871(b) in considerable tension with the narrowly defined control and registration delegation. It would go, moreover, against the plain language of the text to treat a delegation for the "execution" of his functions as a further delegation to define other functions well beyond the Act's specific grants of authority. The authority desired by the Government is inconsistent with the Act's design in other fundamental respects, *e.g.*, the Attorney General must share power with, and in some respect defer to, the Secretary, whose functions are likewise delineated and confined by the Act. Postenactment congressional commentary on the CSA's regulation of medical practice is also at odds with the Attorney General's claimed authority. The Government's claim that the Attorney General's decision is a legal, not medical, one does not suffice, for the Interpretive Rule places extensive reliance on medical judgments and views of the medical community in concluding that assisted suicide is not a legitimate medical purpose. The idea that Congress gave him such broad and unusual authority through an implicit delegation is not sustainable. The importance of the issue of physician-assisted suicide makes the oblique form of the claimed delegation all the more suspect. Pp. 11–22.

(d) The Attorney General's opinion is unpersuasive under *Skidmore*. The CSA and this Court's case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, the Act manifests no intent to regulate the practice of medicine generally, which is understandable given federalism's structure and limitations. The CSA's structure and operation presume and rely upon a functioning medical profession regulated under the States' police powers. The Federal Government can set uniform standards for regulating health and safety. In connection

Syllabus

with the CSA, however, the only provision in which Congress set general, uniform medical practice standards, 42 U. S. C. §2990bb2a, strengthens the understanding of the CSA as a statute combating recreational drug abuse, and also indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit statutory language. The difficulty in defending the Attorney General's declaration that the CSA impliedly criminalizes physician-assisted suicide is compounded by the Act's consistent delegation of medical judgments to the Secretary and its otherwise careful allocation of powers for enforcing the CSA's limited objectives. The Government's contention that the terms "medical" or "medicine" refer to a healing or curative art, and thus cannot embrace the intentional hastening of a patient's death, rests on a reading of 21 U. S. C. §829(a)'s prescription requirement without the illumination of the rest of the statute. Viewed in context, that requirement is better understood as ensuring that patients use controlled substances under a doctor's supervision so as to prevent addiction and recreational abuse. To read prescriptions for assisted suicide as "drug abuse" under the CSA is discordant with the phrase's consistent use throughout the Act, not to mention its ordinary meaning. The Government's interpretation of the prescription requirement also fails under the objection that the Attorney General is an unlikely recipient of such broad authority, given the Secretary's primacy in shaping medical policy under the CSA and the Act's otherwise careful allocation of decisionmaking powers. Pp. 22–28.

368 F. 3d 1118, affirmed.

KENNEDY, J., delivered the opinion of the Court, in which STEVENS, O'CONNOR, SOUTER, GINSBURG, and BREYER, JJ., joined. SCALIA, J., filed a dissenting opinion, in which ROBERTS, C. J., and THOMAS, J., joined. THOMAS, J., filed a dissenting opinion.

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 04–623

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL., PETITIONERS *v.* OREGON ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

[January 17, 2006]

JUSTICE KENNEDY delivered the opinion of the Court.

The question before us is whether the Controlled Substances Act allows the United States Attorney General to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide, notwithstanding a state law permitting the procedure. As the Court has observed, "Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide." *Washington* v. *Glucksberg*, 521 U. S. 702, 735 (1997). The dispute before us is in part a product of this political and moral debate, but its resolution requires an inquiry familiar to the courts: interpreting a federal statute to determine whether Executive action is authorized by, or otherwise consistent with, the enactment.

In 1994, Oregon became the first State to legalize assisted suicide when voters approved a ballot measure enacting the Oregon Death With Dignity Act (ODWDA). Ore. Rev. Stat. §127.800 *et seq.* (2003). ODWDA, which survived a 1997 ballot measure seeking its repeal, exempts from civil or criminal liability state-licensed physi-

cians who, in compliance with the specific safeguards in ODWDA, dispense or prescribe a lethal dose of drugs upon the request of a terminally ill patient.

The drugs Oregon physicians prescribe under ODWDA are regulated under a federal statute, the Controlled Substances Act (CSA or Act). 84 Stat. 1242, as amended, 21 U. S. C. §801 *et seq.* The CSA allows these particular drugs to be available only by a written prescription from a registered physician. In the ordinary course the same drugs are prescribed in smaller doses for pain alleviation.

A November 9, 2001 Interpretive Rule issued by the Attorney General addresses the implementation and enforcement of the CSA with respect to ODWDA. It determines that using controlled substances to assist suicide is not a legitimate medical practice and that dispensing or prescribing them for this purpose is unlawful under the CSA. The Interpretive Rule's validity under the CSA is the issue before us.

I

A

We turn first to the text and structure of the CSA. Enacted in 1970 with the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances, the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules. *Gonzales* v. *Raich*, 545 U. S. ____, ___ (2005) (slip op., at 9–10); 21 U. S. C. §841 (2000 ed. and Supp. II); 21 U. S. C. §844. The Act places substances in one of five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision. Schedule I contains the most severe restrictions on access and use, and Schedule V the least. *Raich*, *supra*, at ___ (slip op., at 11); 21

U. S. C. §812. Congress classified a host of substances when it enacted the CSA, but the statute permits the Attorney General to add, remove, or reschedule substances. He may do so, however, only after making particular findings, and on scientific and medical matters he is required to accept the findings of the Secretary of Health and Human Services (Secretary). These proceedings must be on the record after an opportunity for comment. See 21 U. S. C. A. §811 (main ed. and Supp. 2005).

The present dispute involves controlled substances listed in Schedule II, substances generally available only pursuant to a written, nonrefillable prescription by a physician. 21 U. S. C. §829(a). A 1971 regulation promulgated by the Attorney General requires that every prescription for a controlled substance "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR §1306.04(a) (2005).

To prevent diversion of controlled substances with medical uses, the CSA regulates the activity of physicians. To issue lawful prescriptions of Schedule II drugs, physicians must "obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him." 21 U. S. C. §822(a)(2). The Attorney General may deny, suspend, or revoke this registration if, as relevant here, the physician's registration would be "inconsistent with the public interest." §824(a)(4); §822(a)(2). When deciding whether a practitioner's registration is in the public interest, the Attorney General "shall" consider:

> "(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> "(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

"(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

"(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

"(5) Such other conduct which may threaten the public health and safety." §823(f).

The CSA explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its preemption provision.

"No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together." §903.

B

Oregon voters enacted ODWDA in 1994. For Oregon residents to be eligible to request a prescription under ODWDA, they must receive a diagnosis from their attending physician that they have an incurable and irreversible disease that, within reasonable medical judgment, will cause death within six months. Ore. Rev. Stat. §§127.815, 127.800(12) (2003). Attending physicians must also determine whether a patient has made a voluntary request, ensure a patient's choice is informed, and refer patients to counseling if they might be suffering from a psychological disorder or depression causing impaired judgment. §§127.815, 127.825. A second "consulting" physician must examine the patient and the medical record and confirm the attending physician's conclusions. §127.800(8). Oregon physicians may dispense or issue a prescription for the

requested drug, but may not administer it. §§127.815(1), 127.880.

The reviewing physicians must keep detailed medical records of the process leading to the final prescription, §127.855, records that Oregon's Department of Human Services reviews, §127.865. Physicians who dispense medication pursuant to ODWDA must also be registered with both the State's Board of Medical Examiners and the federal Drug Enforcement Administration (DEA). §127.815(1)(1). In 2004, 37 patients ended their lives by ingesting a lethal dose of medication prescribed under ODWDA. Oregon Dept. of Human Servs., Seventh Annual Report on Oregon's Death with Dignity Act 20 (Mar. 10, 2005).

C

In 1997, Members of Congress concerned about ODWDA invited the DEA to prosecute or revoke the CSA registration of Oregon physicians who assist suicide. They contended that hastening a patient's death is not legitimate medical practice, so prescribing controlled substances for that purpose violates the CSA. Letter from Sen. Orrin Hatch and Rep. Henry Hyde to Thomas A. Constantine (July 25, 1997), reprinted in Hearings on S. 2151 before the Senate Committee on the Judiciary, 105th Cong., 2d Sess., 2–3 (1999) (hereinafter Hearings). The letter received an initial, favorable response from the director of the DEA, see Letter from Thomas A. Constantine to Sen. Orrin Hatch (Nov. 5, 1997), Hearings 4–5, but Attorney General Reno considered the matter and concluded that the DEA could not take the proposed action because the CSA did not authorize it to "displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice," Letter from Attorney General Janet Reno to Sen. Orrin Hatch, on Oregon's Death with

Dignity Act (June 5, 1998), Hearings 5–6. Legislation was then introduced to grant the explicit authority Attorney General Reno found lacking; but it failed to pass. See H. R. 4006, 105th Cong., 2d Sess. (1998); H. R. 2260, 106th Cong., 1st Sess. (1999).

In 2001, John Ashcroft was appointed Attorney General. Perhaps because Mr. Ashcroft had supported efforts to curtail assisted suicide while serving as a Senator, see, *e.g.*, 143 Cong. Rec. 5589–5590 (1997) (remarks of Sen. Ashcroft), Oregon Attorney General Hardy Myers wrote him to request a meeting with Department of Justice officials should the Department decide to revisit the application of the CSA to assisted suicide. Letter of Feb. 2, 2001, App. to Brief for Patient-Respondents in Opposition 55a. Attorney General Myers received a reply letter from one of Attorney General Ashcroft's advisers writing on his behalf, which stated

> "I am aware of no pending legislation in Congress that would prompt a review of the Department's interpretation of the CSA as it relates to physician-assisted suicide. Should such a review be commenced in the future, we would be happy to include your views in that review." Letter from Lori Sharpe (Apr. 17, 2001), *id.*, at 58a.

On November 9, 2001, without consulting Oregon or apparently anyone outside his Department, the Attorney General issued an Interpretive Rule announcing his intent to restrict the use of controlled substances for physician-assisted suicide. Incorporating the legal analysis of a memorandum he had solicited from his Office of Legal Counsel, the Attorney General ruled

> "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the

> Controlled Substances Act. Such conduct by a physician registered to dispense controlled substances may 'render his registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation under 21 U. S. C. 824(a)(4). The Attorney General's conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted." 66 Fed. Reg. 56608 (2001).

There is little dispute that the Interpretive Rule would substantially disrupt the ODWDA regime. Respondents contend, and petitioners do not dispute, that every prescription filled under ODWDA has specified drugs classified under Schedule II. A physician cannot prescribe the substances without DEA registration, and revocation or suspension of the registration would be a severe restriction on medical practice. Dispensing controlled substances without a valid prescription, furthermore, is a federal crime. See, *e.g.*, 21 U. S. C. §841(a)(1) (2000 ed., Supp. II); *United States* v. *Moore*, 423 U. S. 122 (1975).

In response the State of Oregon, joined by a physician, a pharmacist, and some terminally ill patients, all from Oregon, challenged the Interpretive Rule in federal court. The United States District Court for the District of Oregon entered a permanent injunction against the Interpretive Rule's enforcement.

A divided panel of the Court of Appeals for the Ninth Circuit granted the petitions for review and held the Interpretive Rule invalid. *Oregon* v. *Ashcroft*, 368 F. 3d 1118 (2004). It reasoned that, by making a medical procedure authorized under Oregon law a federal offense, the Interpretive Rule altered the "'"usual constitutional balance between the States and the Federal Government"'" without the requisite clear statement that the CSA authorized

such action. *Id.*, at 1124–1125 (quoting *Gregory* v. *Ashcroft*, 501 U. S. 452, 460 (1991) (in turn quoting *Atascadero State Hospital* v. *Scanlon*, 473 U. S. 234, 242 (1985))). The Court of Appeals held in the alternative that the Interpretive Rule could not be squared with the plain language of the CSA, which targets only conventional drug abuse and excludes the Attorney General from decisions on medical policy. 368 F. 3d, at 1125–1129.

We granted the Government's petition for certiorari. 543 U. S. 1145 (2005).

II

Executive actors often must interpret the enactments Congress has charged them with enforcing and implementing. The parties before us are in sharp disagreement both as to the degree of deference we must accord the Interpretive Rule's substantive conclusions and whether the Rule is authorized by the statutory text at all. Although balancing the necessary respect for an agency's knowledge, expertise, and constitutional office with the courts' role as interpreter of laws can be a delicate matter, familiar principles guide us. An administrative rule may receive substantial deference if it interprets the issuing agency's own ambiguous regulation. *Auer* v. *Robbins*, 519 U. S. 452, 461–463 (1997). An interpretation of an ambiguous statute may also receive substantial deference. *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–845 (1984). Deference in accordance with *Chevron*, however, is warranted only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States* v. *Mead Corp.*, 533 U. S. 218, 226–227 (2001). Otherwise, the interpretation is "entitled to respect" only to the extent it has the "power to persuade." *Skidmore* v.

Swift & Co., 323 U. S. 134, 140 (1944).

A

The Government first argues that the Interpretive Rule is an elaboration of one of the Attorney General's own regulations, 21 CFR §1306.04 (2005), which requires all prescriptions be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." As such, the Government says, the Interpretive Rule is entitled to considerable deference in accordance with *Auer*.

In our view *Auer* and the standard of deference it accords to an agency are inapplicable here. *Auer* involved a disputed interpretation of the Fair Labor Standards Act of 1938 as applied to a class of law enforcement officers. Under regulations promulgated by the Secretary of Labor, an exemption from overtime pay depended, in part, on whether the employees met the "salary basis" test. 519 U. S., at 454–455. In this Court the Secretary of Labor filed an *amicus* brief explaining why, in his view, the regulations gave exempt status to the officers. *Id.*, at 461. We gave weight to that interpretation, holding that because the applicable test was "a creature of the Secretary's own regulations, his interpretation of it is, under our jurisprudence, controlling unless plainly erroneous or inconsistent with the regulation." *Ibid.* (internal quotation marks omitted).

In *Auer*, the underlying regulations gave specificity to a statutory scheme the Secretary was charged with enforcing and reflected the considerable experience and expertise the Department of Labor had acquired over time with respect to the complexities of the Fair Labor Standards Act. Here, on the other hand, the underlying regulation does little more than restate the terms of the statute itself. The language the Interpretive Rule addresses comes from Congress, not the Attorney General, and the near-

equivalence of the statute and regulation belies the Government's argument for *Auer* deference.

The Government does not suggest that its interpretation turns on any difference between the statutory and regulatory language. The CSA allows prescription of drugs only if they have a "currently accepted medical use," 21 U. S. C. §812(b); requires a "medical purpose" for dispensing the least controlled substances of those on the schedules, §829(c); and, in its reporting provision, defines a "valid prescription" as one "issued for a legitimate medical purpose," §830(b)(3)(A)(ii). Similarly, physicians are considered to be acting as practitioners under the statute if they dispense controlled substances "in the course of professional practice." §802(21). The regulation uses the terms "legitimate medical purpose" and "the course of professional practice," *ibid.*, but this just repeats two statutory phrases and attempts to summarize the others. It gives little or no instruction on a central issue in this case: Who decides whether a particular activity is in "the course of professional practice" or done for a "legitimate medical purpose"? Since the regulation gives no indication how to decide this issue, the Attorney General's effort to decide it now cannot be considered an interpretation of the regulation. Simply put, the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute. An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.

Furthermore, as explained below, if there is statutory authority to issue the Interpretive Rule it comes from the 1984 amendments to the CSA that gave the Attorney General authority to register and deregister physicians based on the public interest. The regulation was enacted before those amendments, so the Interpretive Rule cannot

be justified as indicative of some intent the Attorney General had in 1971. That the current interpretation runs counter to the "intent at the time of the regulation's promulgation," is an additional reason why *Auer* deference is unwarranted. *Thomas Jefferson Univ.* v. *Shalala*, 512 U. S. 504, 512 (1994) (internal quotation marks omitted). Deference under *Auer* being inappropriate, we turn to the question whether the Interpretive Rule, on its own terms, is a permissible interpretation of the CSA.

B

Just as the Interpretive Rule receives no deference under *Auer*, neither does it receive deference under *Chevron*. If a statute is ambiguous, judicial review of administrative rulemaking often demands *Chevron* deference; and the rule is judged accordingly. All would agree, we should think, that the statutory phrase "legitimate medical purpose" is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense. *Chevron* deference, however, is not accorded merely because the statute is ambiguous and an administrative official is involved. To begin with, the rule must be promulgated pursuant to authority Congress has delegated to the official. *Mead*, 533 U. S., at 226–227.

The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.

The starting point for this inquiry is, of course, the language of the delegation provision itself. In many cases authority is clear because the statute gives an agency broad power to enforce all provisions of the statute. See, *e.g.*, *National Cable & Telecommunications Assn.* v. *Brand X Internet Services*, 545 U. S. ___, ___ (2005) (slip op., at 8)

(explaining that a Federal Communications Commission regulation received *Chevron* deference because "Congress has delegated to the Commission the authority to . . . 'prescribe such rules and regulations as may be necessary in the public interest to carry out the provisions' of the Act" (quoting 47 U. S. C. §201(b))); *Household Credit Services, Inc.* v. *Pfennig*, 541 U. S. 232, 238 (2004) (giving *Chevron* deference to a Federal Reserve Board regulation where "Congress has expressly delegated to the Board the authority to prescribe regulations . . . as, in the judgment of the Board, 'are necessary or proper to effectuate the purposes of'" the statute (quoting 15 U. S. C. §1604(a))). The CSA does not grant the Attorney General this broad authority to promulgate rules.

The CSA gives the Attorney General limited powers, to be exercised in specific ways. His rulemaking authority under the CSA is described in two provisions: (1) "The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals," 21 U. S. C. A. §821 (Supp. 2005); and (2) "The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter," 21 U. S. C. §871(b). As is evident from these sections, Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the CSA. Rather, he can promulgate rules relating only to "registration" and "control," and "for the efficient execution of his functions" under the statute.

Turning first to the Attorney General's authority to make regulations for the "control" of drugs, this delegation cannot sustain the Interpretive Rule's attempt to define standards of medical practice. Control is a term of art in the CSA. "As used in this subchapter," §802—the sub-

chapter that includes §821—

> "The term 'control' means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise." §802(5).

To exercise his scheduling power, the Attorney General must follow a detailed set of procedures, including requesting a scientific and medical evaluation from the Secretary. See 21 U. S. C. A. §§811, 812 (main ed. and Supp. 2005). The statute is also specific as to the manner in which the Attorney General must exercise this authority: "Rules of the Attorney General under this subsection [regarding scheduling] shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the Administrative Procedure Act, 5 U. S. C. §553]." 21 U. S. C. §811(a). The Interpretive Rule now under consideration does not concern the scheduling of substances and was not issued after the required procedures for rules regarding scheduling, so it cannot fall under the Attorney General's "control" authority.

Even if "control" in §821 were understood to signify something other than its statutory definition, it would not support the Interpretive Rule. The statutory references to "control" outside the scheduling context make clear that the Attorney General can establish controls "against diversion," *e.g.*, §823(a)(1), but do not give him authority to define diversion based on his view of legitimate medical practice. As explained below, the CSA's express limitations on the Attorney General's authority, and other indications from the statutory scheme, belie any notion that the Attorney General has been granted this implicit authority. Indeed, if "control" were given the expansive meaning required to sustain the Interpretive Rule, it would transform the carefully described limits on the

Attorney General's authority over registration and scheduling into mere suggestions.

We turn, next, to the registration provisions of the CSA. Before 1984, the Attorney General was required to register any physician who was authorized by his State. The Attorney General could only deregister a physician who falsified his application, was convicted of a felony relating to controlled substances, or had his state license or registration revoked. See 84 Stat. 1255. The CSA was amended in 1984 to allow the Attorney General to deny registration to an applicant "if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U. S. C. §823(f). Registration may also be revoked or suspended by the Attorney General on the same grounds. §824(a)(4). In determining consistency with the public interest, the Attorney General must, as discussed above, consider five factors, including: the State's recommendation; compliance with state, federal, and local laws regarding controlled substances; and public health and safety. §823(f).

The Interpretive Rule cannot be justified under this part of the statute. It does not undertake the five-factor analysis and concerns much more than registration. Nor does the Interpretive Rule on its face purport to be an application of the registration provision in §823(f). It is, instead, an interpretation of the substantive federal law requirements (under 21 CFR §1306.04 (2005)) for a valid prescription. It begins by announcing that assisting suicide is not a "legitimate medical purpose" under §1306.04, and that dispensing controlled substances to assist a suicide violates the CSA. 66 Fed. Reg. 56608 (2001). Violation is a criminal offense, and often a felony, under 21 U. S. C. §841 (2000 ed. and Supp. II). The Interpretive Rule thus purports to declare that using controlled substances for physician-assisted suicide is a crime, an authority that goes well beyond the Attorney General's statutory power

to register or deregister.

The Attorney General's deregistration power, of course, may carry implications for criminal enforcement because if a physician dispenses a controlled substance after he is deregistered, he violates §841. The Interpretive Rule works in the opposite direction, however: it declares certain conduct criminal, placing in jeopardy the registration of any physician who engages in that conduct. To the extent the Interpretive Rule concerns registration, it simply states the obvious because one of the five factors the Attorney General must consider in deciding the "public interest" is "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." 21 U. S. C. §823(f)(4). The problem with the design of the Interpretive Rule is that it cannot, and does not, explain why the Attorney General has the authority to decide what constitutes an underlying violation of the CSA in the first place. The explanation the Government seems to advance is that the Attorney General's authority to decide whether a physician's actions are inconsistent with the "public interest" provides the basis for the Interpretive Rule.

By this logic, however, the Attorney General claims extraordinary authority. If the Attorney General's argument were correct, his power to deregister necessarily would include the greater power to criminalize even the actions of registered physicians, whenever they engage in conduct he deems illegitimate. This power to criminalize—unlike his power over registration, which must be exercised only after considering five express statutory factors—would be unrestrained. It would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside "the course of professional practice," and therefore a criminal violation of the CSA. See *Federal*

Maritime Comm'n v. *Seatrain Lines, Inc.*, 411 U. S. 726, 744 (1973) ("In light of these specific grants of . . . authority, we are unwilling to construe the ambiguous provisions . . . to serve this purpose [of creating further authority]—a purpose for which it obviously was not intended").

Sutton v. *United Air Lines, Inc.*, 527 U. S. 471 (1999), is instructive. The statute at issue was the Americans with Disabilities Act of 1990 (ADA), which, like the CSA, divides interpretive authority among various Executive actors. The Court relied on "the terms and structure of the ADA" to decide that neither the Equal Employment Opportunity Commission, nor any other agency had authority to define "disability" in the ADA. *Id.*, at 479. Specifically, the delegating provision stated that the EEOC "shall issue regulations . . . to carry out this subchapter," 42 U. S. C. §12116, and the section of the statute defining "disability" was in a different subchapter. The Court did not accept the idea that because "the employment subchapter, *i.e.*, '*this* subchapter,' includes other provisions that use the defined terms, . . . [t]he EEOC might elaborate, through regulations, on the meaning of 'disability' . . . if elaboration is needed in order to 'carry out' the substantive provisions of 'this subchapter.'" 527 U. S., at 514 (BREYER, J., dissenting). See also *Adams Fruit Co.* v. *Barrett*, 494 U. S. 638, 649–650 (1990) (holding that a delegation of authority to promulgate motor vehicle safety *"standards"* did not include the authority to decide the pre-emptive scope of the federal statute because "[n]o such delegation regarding [the statute's] enforcement provisions is evident in the statute").

The same principle controls here. It is not enough that the terms "public interest," "public health and safety," and "Federal law" are used in the part of the statute over which the Attorney General has authority. The statutory terms "public interest" and "public health" do not call on the Attorney General, or any other Executive official, to

make an independent assessment of the meaning of federal law. The Attorney General did not base the Interpretive Rule on an application of the five-factor test generally, or the "public health and safety" factor specifically. Even if he had, it is doubtful the Attorney General could cite the "public interest" or "public health" to deregister a physician simply because he deemed a controversial practice permitted by state law to have an illegitimate medical purpose.

As for the federal law factor, though it does require the Attorney General to decide "[c]ompliance" with the law, it does not suggest that he may decide what the law says. Were it otherwise, the Attorney General could authoritatively interpret "State" and "local laws," which are also included in 21 U. S. C. §823(f), despite the obvious constitutional problems in his doing so. Just as he must evaluate compliance with federal law in deciding about registration, the Attorney General must as surely evaluate compliance with federal law in deciding whether to prosecute; but this does not entitle him to *Chevron* deference. See *Crandon* v. *United States*, 494 U. S. 152, 177 (1990) (SCALIA, J., concurring in judgment) ("The Justice Department, of course, has a very specific responsibility to determine for itself what this statute means, in order to decide when to prosecute; but we have never thought that the interpretation of those charged with prosecuting criminal statutes is entitled to deference").

The limits on the Attorney General's authority to define medical standards for the care and treatment of patients bear also on the proper interpretation of §871(b). This section allows the Attorney General to best determine how to execute "his functions." It is quite a different matter, however, to say that the Attorney General can define the substantive standards of medical practice as part of his authority. To find a delegation of this extent in §871 would put that part of the statute in considerable tension

with the narrowly defined delegation concerning control and registration. It would go, moreover, against the plain language of the text to treat a delegation for the "execution" of his functions as a further delegation to define other functions well beyond the statute's specific grants of authority. When Congress chooses to delegate a power of this extent, it does so not by referring back to the administrator's functions but by giving authority over the provisions of the statute he is to interpret. *See, e.g., National Cable & Telecommunications Assn.*, 545 U. S. ___; *Household Credit Services*, 541 U. S. 232.

The authority desired by the Government is inconsistent with the design of the statute in other fundamental respects. The Attorney General does not have the sole delegated authority under the CSA. He must instead share it with, and in some respects defer to, the Secretary, whose functions are likewise delineated and confined by the statute. The CSA allocates decisionmaking powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary. In the scheduling context, for example, the Secretary's recommendations on scientific and medical matters bind the Attorney General. The Attorney General cannot control a substance if the Secretary disagrees. 21 U. S. C. §811(b). *See* H. R. Rep. No. 91–1444, pt. 1, p. 33 (1970) (the section "is not intended to authorize the Attorney General to undertake or support medical and scientific research [for the purpose of scheduling], which is within the competence of the Department of Health, Education, and Welfare").

In a similar vein the 1970 Act's regulation of medical practice with respect to drug rehabilitation gives the Attorney General a limited role; for it is the Secretary who, after consultation with the Attorney General and national medical groups, "determine[s] the appropriate methods of professional practice in the medical treatment

of . . . narcotic addiction." 42 U. S. C. §290bb–2a; see 21 U. S. C. §823(g) (2000 ed. and Supp. II) (stating that the Attorney General shall register practitioners who dispense drugs for narcotics treatment when the Secretary has determined the applicant is qualified to treat addicts and the Attorney General has concluded the applicant will comply with record keeping and security regulations); *Moore*, 423 U. S., at 144 (noting that in enacting the addiction-treatment provisions, Congress sought to change the fact "that 'criminal prosecutions' in the past had turned on the opinions of federal prosecutors"); H. R. Rep. No. 93–884, p. 6 (1974) ("This section preserves the distinctions found in the [CSA] between the functions of the Attorney General and the Secretary . . . . All decisions of a medical nature are to be made by the Secretary . . . . Law enforcement decisions respecting the security of stocks of narcotics drugs and the maintenance of records on such drugs are to be made by the Attorney General").

Post enactment congressional commentary on the CSA's regulation of medical practice is also at odds with the Attorney General's claimed authority to determine appropriate medical standards. In 1978, in preparation for ratification of the Convention on Psychotropic Substances, Feb. 21, 1971, [1979–1980] 32 U. S. T. 543, T. I. A. S. No. 9725, Congress decided it would implement the United States' compliance through "the framework of the procedures and criteria for classification of substances provided in the" CSA. 21 U. S. C. §801a(3). It did so to ensure that "nothing in the Convention will interfere with ethical medical practice in this country as determined by [the Secretary] on the basis of a consensus of the views of the American medical and scientific community." *Ibid.*

The structure of the CSA, then, conveys unwillingness to cede medical judgments to an Executive official who lacks medical expertise. In interpreting statutes that divide authority, the Court has recognized: "Because

historical familiarity and policymaking expertise account in the first instance for the presumption that Congress delegates interpretive lawmaking power to the agency rather than to the reviewing court, we presume here that Congress intended to invest interpretive power in the administrative actor in the best position to develop these attributes." *Martin* v. *Occupational Safety and Health Review Comm'n*, 499 U. S. 144, 153 (1991) (citations omitted). This presumption works against a conclusion that the Attorney General has authority to make quintessentially medical judgments.

The Government contends the Attorney General's decision here is a legal, not a medical, one. This generality, however, does not suffice. The Attorney General's Interpretive Rule, and the Office of Legal Counsel memo it incorporates, place extensive reliance on medical judgments and the views of the medical community in concluding that assisted suicide is not a "legitimate medical purpose." See 66 Fed. Reg. 56608 (noting the "medical" distinctions between assisting suicide and giving sufficient medication to alleviate pain); Memorandum from Office of Legal Counsel to Attorney General (June 27, 2001), App. to Pet. for Cert. 121a–122a, and n. 17 (discussing the "Federal medical policy" against physician-assisted suicide), *id.*, at 124a–130a (examining views of the medical community). This confirms that the authority claimed by the Attorney General is both beyond his expertise and incongruous with the statutory purposes and design.

The idea that Congress gave the Attorney General such broad and unusual authority through an implicit delegation in the CSA's registration provision is not sustainable. "Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *American Trucking Assns., Inc.*, 531 U. S. 457, 468 (2001); see *FDA* v. *Brown & Williamson*

Tobacco Corp., 529 U. S. 120, 160 (2000) ("[W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion").

The importance of the issue of physician-assisted suicide, which has been the subject of an "earnest and profound debate" across the country, *Glucksberg*, 521 U. S., at 735, makes the oblique form of the claimed delegation all the more suspect. Under the Government's theory, moreover, the medical judgments the Attorney General could make are not limited to physician-assisted suicide. Were this argument accepted, he could decide whether any particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered. This would occur, under the Government's view, despite the statute's express limitation of the Attorney General's authority to registration and control, with attendant restrictions on each of those functions, and despite the statutory purposes to combat drug abuse and prevent illicit drug trafficking.

We need not decide whether *Chevron* deference would be warranted for an interpretation issued by the Attorney General concerning matters closer to his role under the CSA, namely preventing doctors from engaging in illicit drug trafficking. In light of the foregoing, however, the CSA does not give the Attorney General authority to issue the Interpretive Rule as a statement with the force of law.

If, in the course of exercising his authority, the Attorney General uses his analysis in the Interpretive Rule only for guidance in deciding when to prosecute or deregister, then the question remains whether his substantive interpretation is correct. Since the Interpretive Rule was not promulgated pursuant to the Attorney General's authority, its interpretation of "legitimate medical purpose" does not receive *Chevron* deference. Instead, it receives deference only in accordance with *Skidmore*. "The weight of such a

judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." 323 U. S., at 140; see also *Mead,* 533 U. S., at 235 (noting that an opinion receiving *Skidmore* deference may "claim the merit of its writer's thoroughness, logic, and expertness, its fit with prior interpretations, and any other sources of weight"). The deference here is tempered by the Attorney General's lack of expertise in this area and the apparent absence of any consultation with anyone outside the Department of Justice who might aid in a reasoned judgment. In any event, under *Skidmore*, we follow an agency's rule only to the extent it is persuasive, see *Christensen* v. *Harris County,* 529 U. S. 576, 587 (2000); and for the reasons given and for further reasons set out below, we do not find the Attorney General's opinion persuasive.

III

As we have noted before, the CSA "repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic in illicit drugs." *Raich*, 545 U. S., at ___ (slip op., at 9). In doing so, Congress sought to "conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Ibid.* It comes as little surprise, then, that we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug "'pusher'" instead of a physician. *Moore*, 423 U. S., at 143. In *Moore*, we addressed a situation in which a doctor "sold drugs, not for legitimate purposes, but primarily for the profits to be derived therefrom." *Id.*, at 135 (quoting H. R. Rep. No. 91–1444, pt. 1, at 10; internal quotation marks omitted). There the defendant, who had engaged in large-scale overprescribing of methadone,

"concede[d] in his brief that he did not observe generally accepted medical practices." 423 U. S., at 126. And in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U. S. 483 (2001), Congress' express determination that marijuana had no accepted medical use foreclosed any argument about statutory coverage of drugs available by a doctor's prescription.

In deciding whether the CSA can be read as prohibiting physician-assisted suicide, we look to the statute's text and design. The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States "'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 475 (1996) (quoting *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U. S. 724, 756 (1985)).

The structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers. The Attorney General can register a physician to dispense controlled substances "if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U. S. C. §823(f). When considering whether to revoke a physician's registration, the Attorney General looks not just to violations of federal drug laws; but he "shall" also consider "[t]he recommendation of the appropriate state licensing board or professional disciplinary authority" and the registrant's compliance with state and local drug laws. *Ibid.* The very definition of a "practitio-

ner" eligible to prescribe includes physicians "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices" to dispense controlled substances. §802(21). Further cautioning against the conclusion that the CSA effectively displaces the States' general regulation of medical practice is the Act's pre-emption provision, which indicates that, absent a positive conflict, none of the Act's provisions should be "construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State." §903.

Oregon's regime is an example of the state regulation of medical practice that the CSA presupposes. Rather than simply decriminalizing assisted suicide, ODWDA limits its exercise to the attending physicians of terminally ill patients, physicians who must be licensed by Oregon's Board of Medical Examiners. Ore. Rev. Stat. §§127.815, 127.800(10) (2003). The statute gives attending physicians a central role, requiring them to provide prognoses and prescriptions, give information about palliative alternatives and counseling, and ensure patients are competent and acting voluntarily. §127.815. Any eligible patient must also get a second opinion from another registered physician, §127.820, and the statute's safeguards require physicians to keep and submit to inspection detailed records of their actions, §§127.855, 127.865.

Even though regulation of health and safety is "primarily, and historically, a matter of local concern," *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 719 (1985), there is no question that the Federal Government can set uniform national standards in these areas. See *Raich, supra*, at ___ (slip op., at 6). In connection to the CSA, however, we find only one area in which Congress set general, uniform standards of medical prac-

tice. Title I of the Comprehensive Drug Abuse Prevention and Control Act of 1970, of which the CSA was Title II, provides that

> "[The Secretary], after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress." §4, 84 Stat. 1241, codified at 42 U. S. C. §290bb–2a.

This provision strengthens the understanding of the CSA as a statute combating recreational drug abuse, and also indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute.

In the face of the CSA's silence on the practice of medicine generally and its recognition of state regulation of the medical profession it is difficult to defend the Attorney General's declaration that the statute impliedly criminalizes physician-assisted suicide. This difficulty is compounded by the CSA's consistent delegation of medical judgments to the Secretary and its otherwise careful allocation of powers for enforcing the limited objects of the CSA. See Part II–B, *supra*. The Government's attempt to meet this challenge rests, for the most part, on the CSA's requirement that every Schedule II drug be dispensed pursuant to a "written prescription of a practitioner." 21 U. S. C. §829(a). A prescription, the Government argues, necessarily implies that the substance is being made available to a patient for a legitimate medical purpose. The statute, in this view, requires an anterior judgment about the term "medical" or "medicine." The Government contends ordinary usage of these words ineluctably refers

to a healing or curative art, which by these terms cannot embrace the intentional hastening of a patient's death. It also points to the teachings of Hippocrates, the positions of prominent medical organizations, the Federal Government, and the judgment of the 49 States that have not legalized physician-assisted suicide as further support for the proposition that the practice is not legitimate medicine. See Brief for Petitioners 22–24; Memorandum from Office of Legal Counsel to Attorney General, App. to Pet. for Cert. 124a–130a.

On its own, this understanding of medicine's boundaries is at least reasonable. The primary problem with the Government's argument, however, is its assumption that the CSA impliedly authorizes an Executive officer to bar a use simply because it may be inconsistent with one reasonable understanding of medical practice. Viewed alone, the prescription requirement may support such an understanding, but statutes "should not be read as a series of unrelated and isolated provisions." *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 570 (1995). The CSA's substantive provisions and their arrangement undermine this assertion of an expansive federal authority to regulate medicine.

The statutory criteria for deciding what substances are controlled, determinations which are central to the Act, consistently connect the undefined term "drug abuse" with addiction or abnormal effects on the nervous system. When the Attorney General schedules drugs, he must consider a substance's psychic or physiological dependence liability. 21 U. S. C. §811(c)(7). To classify a substance in Schedules II through V, the Attorney General must find abuse of the drug leads to psychological or physical dependence. §812(b). Indeed, the differentiation of Schedules II through V turns in large part on a substance's habit-forming potential: The more addictive a substance, the stricter the controls. *Ibid.* When Congress wanted to

extend the CSA's regulation to substances not obviously habit forming or psychotropic, moreover, it relied not on Executive ingenuity, but rather on specific legislation. See §1902(a) of the Anabolic Steroids Control Act of 1990, 104 Stat. 4851 (placing anabolic steroids in Schedule III).

The statutory scheme with which the CSA is intertwined further confirms a more limited understanding of the prescription requirement. When the Secretary considers FDA approval of a substance with "stimulant, depressant, or hallucinogenic effect," he must forward the information to the Attorney General for possible scheduling. Shedding light on Congress' understanding of drug abuse, this requirement appears under the heading "Abuse potential." 21 U. S. C. §811(f). Similarly, when Congress prepared to implement the Convention on Psychotropic Substances, it did so through the CSA. §801a.

The Interpretive Rule rests on a reading of the prescription requirement that is persuasive only to the extent one scrutinizes the provision without the illumination of the rest of the statute. See *Massachusetts* v. *Morash*, 490 U. S. 107, 114–115 (1989). Viewed in its context, the prescription requirement is better understood as a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses. See *Moore*, 423 U. S., at 135, 143. To read prescriptions for assisted suicide as constituting "drug abuse" under the CSA is discordant with the phrase's consistent use throughout the statute, not to mention its ordinary meaning.

The Government's interpretation of the prescription requirement also fails under the objection that the Attorney General is an unlikely recipient of such broad authority, given the Secretary's primacy in shaping medical policy under the CSA, and the statute's otherwise careful alloca-

tion of decisionmaking powers. Just as the conventions of expression indicate that Congress is unlikely to alter a statute's obvious scope and division of authority through muffled hints, the background principles of our federal system also belie the notion that Congress would use such an obscure grant of authority to regulate areas traditionally supervised by the States' police power. It is unnecessary even to consider the application of clear statement requirements, see, *e.g.*, *United States* v. *Bass*, 404 U. S. 336, 349 (1971); cf. *BFP* v. *Resolution Trust Corporation*, 511 U. S. 531, 544–546 (1994), or presumptions against preemption, see, *e.g.*, *Rush Prudential HMO, Inc.* v. *Moran*, 536 U. S. 355, 387 (2002), to reach this commonsense conclusion. For all these reasons, we conclude the CSA's prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct.

IV

The Government, in the end, maintains that the prescription requirement delegates to a single Executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality. The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it.

The judgment of the Court of Appeals is

Affirmed.

SUPREME COURT OF THE UNITED STATES

No. 04–623

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL., PETITIONERS *v.* OREGON ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

[January 17, 2006]

JUSTICE SCALIA, with whom CHIEF JUSTICE ROBERTS and JUSTICE THOMAS join, dissenting.

The Court concludes that the Attorney General lacked authority to declare assisted suicide illicit under the Controlled Substances Act (CSA), because the CSA is concerned only with "*illicit* drug dealing and trafficking," *ante*, at 23 (emphasis added). This question-begging conclusion is obscured by a flurry of arguments that distort the statute and disregard settled principles of our interpretive jurisprudence.

Contrary to the Court's analysis, this case involves not one but *three* independently sufficient grounds for reversing the Ninth Circuit's judgment. First, the Attorney General's interpretation of "legitimate medical purpose" in 21 CFR §1306.04 (2005) (hereinafter Regulation) is clearly valid, given the substantial deference we must accord it under *Auer* v. *Robbins*, 519 U. S. 452, 461 (1997), and his two remaining conclusions follow naturally from this interpretation. See Part I, *infra*. Second, even if this interpretation of the Regulation is entitled to lesser deference or no deference at all, it is by far the most natural interpretation of the Regulation—whose validity is not challenged here. This interpretation is thus correct even upon *de novo* review. See Part II, *infra*. Third, even if that interpretation of the Regulation were incorrect, the

Attorney General's independent interpretation of the *statutory* phrase "public interest" in 21 U. S. C. §§824(a) and 823(f), and his implicit interpretation of the statutory phrase "public health and safety" in §823(f)(5), are entitled to deference under *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837 (1984), and they are valid under *Chevron*. See Part III, *infra*. For these reasons, I respectfully dissent.

I

The Interpretive Rule issued by the Attorney General (hereinafter Directive) provides in relevant part as follows:

> "For the reasons set forth in the OLC Opinion, I hereby determine that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR §1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA. Such conduct by a physician registered to dispense controlled substances may 'render his registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation under 21 U. S. C. [§]824(a)(4)." 66 Fed. Reg. 56608 (2001).

The Directive thus purports to do three distinct things: (1) to interpret the phrase "legitimate medical purpose" in the Regulation to exclude physician-assisted suicide; (2) to determine that prescribing, dispensing, and administering federally controlled substances to assist suicide violates the CSA; and (3) to determine that participating in physician-assisted suicide may render a practitioner's registration "inconsistent with the public interest" within the meaning of 21 U. S. C. §§823(f) and 824(a)(4) (which incorporates §823(f) by reference). The Court's analysis suffers from an unremitting failure to distinguish among these distinct propositions in the Directive.

As an initial matter, the validity of the Regulation's interpretation of "prescription" in §829 to require a "legitimate medical purpose" is not at issue. Respondents conceded the validity of this interpretation in the lower court, see *Oregon* v. *Ashcroft*, 368 F. 3d 1118, 1133 (CA9 2004), and they have not challenged it here. By its assertion that the Regulation merely restates the statutory standard of 21 U. S. C. §830(b)(3)(A)(ii), see *ante*, at 10, the Court likewise accepts that the "legitimate medical purpose" interpretation for prescriptions is proper. See also *ante*, at 11 (referring to "legitimate medical purpose" as a "statutory phrase"). It is beyond dispute, then, that a "prescription" under §829 must issue for a "legitimate medical purpose."

A

Because the Regulation was promulgated by the Attorney General, and because the Directive purported to interpret the language of the Regulation, see 66 Fed. Reg. 56608, this case calls for the straightforward application of our rule that an agency's interpretation of its own regulations is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer*, *supra*, at 461 (internal quotation marks omitted). The Court reasons that *Auer* is inapplicable because the Regulation "does little more than restate the terms of the statute itself." *Ante*, at 9. "Simply put," the Court asserts, "the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute." *Ante*, at 10.

To begin with, it is doubtful that any such exception to the *Auer* rule exists. The Court cites no authority for it, because there is none. To the contrary, our unanimous decision in *Auer* makes clear that broadly drawn regulations are entitled to no less respect than narrow ones. "A rule requiring the Secretary to construe his own regula-

tions narrowly would make little sense, *since he is free to write the regulations as broadly as he wishes, subject only to the limits imposed by the statute.*" 519 U. S., at 463 (emphasis added).

Even if there were an antiparroting canon, however, it would have no application here. The Court's description of 21 CFR §1306.04 (2005) as a regulation that merely "paraphrase[s] the statutory language," *ante*, at 10, is demonstrably false. In relevant part, the Regulation interprets the word "prescription" as it appears in 21 U. S. C. §829, which governs the dispensation of controlled substances other than those on Schedule I (which may not be dispensed at all). Entitled "[p]rescriptions," §829 requires, with certain exceptions not relevant here, "the written prescription of a practitioner" (usually a medical doctor) for the dispensation of Schedule II substances (§829(a)), "a written or oral prescription" for substances on Schedules III and IV (§829(b)), and no prescription but merely a "medical purpose" for the dispensation of Schedule V substances (§829(c)).

As used in this section, "prescription" is susceptible of at least three reasonable interpretations. First, it might mean any oral or written direction of a practitioner for the dispensation of drugs. See *United States* v. *Moore*, 423 U. S. 122, 137, n. 13 (1975) ("On its face §829 addresses only the form that a prescription must take. . . . [Section] 829 by its terms does not limit the authority of a practitioner"). Second, in light of the requirement of a "medical purpose" for the dispensation of Schedule V substances, see §829(c), it might mean a practitioner's oral or written direction for the dispensation of drugs that the practitioner believes to be for a legitimate medical purpose. See Webster's New International Dictionary 1954 (2d ed. 1950) (hereinafter Webster's Second) (defining "prescription" as "[a] written direction for the preparation and use of a *medicine*"); *id.*, at 1527 (defining "medicine" as "[a]ny

substance or preparation used in *treating disease*") (emphases added). Finally, "prescription" might refer to a practitioner's direction for the dispensation of drugs that serves an *objectively* legitimate medical purpose, regardless of the practitioner's *subjective* judgment about the legitimacy of the anticipated use. See *ibid.*

The Regulation at issue constricts or clarifies the statute by adopting the last and narrowest of these three possible interpretations of the undefined statutory term: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose . . . ." 21 CFR §1306.04(a) (2005). We have previously *acknowledged* that the Regulation gives added content to the text of the statute: "The medical purpose requirement explicit in subsection (c) [of §829] could be implicit in subsections (a) and (b). Regulation §[1]306.04 makes it explicit." *Moore*, *supra*, at 137, n. 13.[1]

The Court points out that the Regulation adopts some of the phrasing employed in unrelated sections of the statute. See *ante*, at 10. This is irrelevant. A regulation that significantly clarifies the meaning of an otherwise ambiguous statutory provision is not a "parroting" regulation, *regardless* of the sources that the agency draws upon for the clarification. Moreover, most of the statutory phrases that the Court cites as appearing in the Regulation, see *ibid.* (citing 21 U. S. C. §§812(b) ("'currently accepted medical use'"), 829(c) ("'medical purpose'"), 802(21) ("'in the course of professional practice'")), are inapposite be-

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[1]To be sure, this acknowledgment did not go far enough, because it overlooked the significance of the word "legitimate," which is most naturally understood to create an objective, *federal* standard for appropriate medical uses. See *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U. S. 30, 43 (1989) ("We start . . . with the general assumption that in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law" (internal quotation marks omitted)).

cause they do *not* "parrot" the *only* phrase in the Regulation that the Directive purported to construe. See 66 Fed. Reg. 56608 ("I hereby determine that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR §1306.04 . . ."). None of them includes the key word "legitimate," which gives the most direct support to the Directive's theory that §829(c) presupposes a uniform federal standard of medical practice.[2]

Since the Regulation does not run afowl (so to speak) of the Court's newly invented prohibition of "parroting"; and since the Directive represents the agency's own interpretation of that concededly valid regulation; the only question remaining is whether that interpretation is "plainly erroneous or inconsistent with the regulation"; otherwise, it is "controlling." *Auer*, *supra*, at 461 (internal quotation marks omitted). This is not a difficult question. The Directive is assuredly valid insofar as it interprets "prescription" to require a medical purpose that is "legitimate" as a matter of *federal* law—since that is an interpretation of "prescription" that we ourselves have adopted. *Webb* v. *United States*, 249 U. S. 96 (1919), was a prosecution

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[2]The only place outside 21 U. S. C. §801 in which the statute uses the phrase "legitimate medical purpose" is in defining the phrase "valid prescription" for purposes of the reporting requirements that apply to mail orders of regulated substances. See §830(b)(3)(A)(ii). The Regulation did not "parrot" this statutory section, because the Regulation was adopted in 1971 and the statutory language was added in 2000. See Brief for Petitioners 17 (citing the Children's Health Act of 2000, §3652, 114 Stat. 1239, 21 U. S. C. §830(b)(3)). But even if the statutory language had predated the Regulation, there would be no "parroting" of that phrase. In using the word "prescription" *without* definition in the much more critical §829, Congress left the task of resolving any ambiguity in that word, used in that context, to the relevant Executive officer. That the officer did so by deeming relevant a technically inapplicable statutory definition contained elsewhere in the statute does not make him a parrot. He has given to the statutory text a meaning it did not explicitly—and perhaps even not necessarily—contain.

under the Harrison Act of a doctor who wrote prescriptions of morphine "for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use," *id.*, at 99. The dispositive issue in the case was whether such authorizations were "prescriptions" within the meaning of §2(b) of the Harrison Act, predecessor to the CSA. *Ibid.* We held that "to call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required." *Id.*, at 99–100. Like the Directive, this interprets "prescription" to require medical purpose that is legitimate as a matter of federal law. And the Directive is also assuredly valid insofar as it interprets "legitimate medical purpose" as a matter of federal law to exclude physician-assisted suicide, because that is not only a permissible but indeed the most natural interpretation of that phrase. See Part II, *infra*.

B

Even if the Regulation merely parroted the statute, and the Directive therefore had to be treated as though it construed the statute directly, see *ante*, at 11, the Directive would still be entitled to deference under *Chevron*. The Court does not take issue with the Solicitor General's contention that no alleged procedural defect, such as the absence of notice-and-comment rulemaking before promulgation of the Directive, renders *Chevron* inapplicable here. See Reply Brief for Petitioners 4 (citing *Barnhart* v. *Walton*, 535 U. S. 212, 219–222 (2002); 5 U. S. C. §553(b)(3)(A) (exempting interpretive rules from notice-and-comment rulemaking)). Instead, the Court holds that the Attorney General lacks interpretive authority to issue the Directive at all, on the ground that the explicit delegation provision, 21 U. S. C. A. §821 (Supp. 2005), limits his rulemaking authority to "registration and control," which (according to the Court) are not implicated by the Directive's interpreta-

tion of the prescription requirement. See *ante*, at 12–14.

Setting aside the implicit delegation inherent in Congress's use of the undefined term "prescription" in §829, the Court's reading of "control" in §821 is manifestly erroneous. The Court urges, *ante*, at 12–13, that "control" is a term defined in part A of the subchapter (entitled "Introductory Provisions") to mean "to add a drug or other substance . . . to a schedule *under part B of this subchapter*," 21 U. S. C. §802(5) (emphasis added). But §821 is not included in "part B of this subchapter," which is entitled "Authority to Control; Standards and Schedules," and consists of the sections related to *scheduling*, 21 U. S. C. A. §§811–814 (main ed. and Supp. 2005), where the statutory definition is uniquely appropriate. Rather, §821 is found in *part C* of the subchapter, §§821–830, entitled "Registration of Manufacturers, Distributors and Dispensers of Controlled Substances," which includes all and only the provisions relating to the "manufacture, distribution, and dispensing of controlled substances," §821. The artificial definition of "control" in §802(5) has no conceivable application to the use of that word in §821. Under that definition, "control" must take a *substance* as its direct object, see 21 U. S. C. §802(5) ("to add a drug or other substance . . . to a schedule")—and that is how "control" is consistently used throughout *part B*. See, *e.g.*, §§811(b) ("proceedings . . . to *control* a drug or other substance"), 811(c) ("each drug or other substance proposed to be *controlled* or removed from the schedules"), 811(d)(1) ("If *control* is required . . . the Attorney General shall issue an order *controlling* such drug . . ."), 812(b) ("Except where *control* is required . . . a drug or other substance may not be placed in any schedule . . ."). In §821, by contrast, the term "control" has as its object, not "a drug or other substance," but rather the *processes* of "manufacture, distribution, and dispensing of controlled substances." It could not be clearer that the artificial definition of "control" in

§802(5) is inapplicable. It makes no sense to speak of "adding the manufacturing, distribution, and dispensing of substances to a schedule." We do not force term-of-art definitions into contexts where they plainly do not fit and produce nonsense. What is obviously intended in §821 is the ordinary meaning of "control"—namely, "[t]o exercise restraining or directing influence over; to dominate; regulate; hence, to hold from action; to curb," Webster's Second 580. "Control" is regularly used in this ordinary sense elsewhere in *part C* of the subchapter. See, *e.g.*, 21 U. S. C. §§823(a)(1), (b)(1), (d)(1), (e)(1), (h)(1) ("maintenance of effective *controls* against diversion"); §§823(a)(5), (d)(5) ("establishment of effective *control* against diversion"); §823(g)(2)(H)(i) ("to exercise supervision or *control* over the practice of medicine"); §830(b)(1)(C) ("a listed chemical under the *control* of the regulated person"); §830(c)(2)(D) ("chemical *control* laws") (emphases added).

When the word is given its ordinary meaning, the Attorney General's interpretation of the prescription requirement of §829 plainly "relat[es] to the . . . *control* of the . . . dispensing of controlled substances," 21 U. S. C. A. §821 (Supp. 2005) (emphasis added), since a prescription is the chief requirement for "dispensing" such drugs, see §829. The same meaning is compelled by the fact that §821 is the first section not of part B of the subchapter, which deals entirely with "control" in the artificial sense, but of part C, every section of which relates to the "registration and control of the manufacture, distribution, and dispensing of controlled substances," §821. See §§822 (persons required to register), 823 (registration requirements), 824 (denial, revocation, or suspension of registration), 825 (labeling and packaging), 826 (production quotas for controlled substances), 827 (recordkeeping and reporting requirements of registrants), 828 (order forms), 829 (prescription requirements), 830 (regulation of listed chemicals and certain machines). It would be peculiar for

the first section of this part to authorize rulemaking for matters covered by the *previous* part. The only sensible interpretation of §821 is that it gives the Attorney General interpretive authority over the provisions of part C, all of which "relat[e] to the registration and control of the manufacture, distribution, and dispensing of controlled substances." These provisions include *both* the prescription requirement of §829, and the criteria for registration and deregistration of §§823 and 824 (as relevant below, see Part III, *infra*).[3]

C

In sum, the Directive's construction of "legitimate medical purpose" is a perfectly valid agency interpretation of its own regulation; and if not that, a perfectly valid agency interpretation of the statute. No one contends that the construction is "plainly erroneous or inconsistent with the regulation," *Bowles* v. *Seminole Rock & Sand Co.*, 325 U. S. 410, 414 (1945), or beyond the scope of ambiguity in the statute, see *Chevron*, 467 U. S., at 843. In fact, as

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[3]The Court concludes that "[e]ven if 'control' in §821 were understood to signify something other than its statutory definition, it would not support the Interpretive Rule." *Ante*, at 13. That conclusion rests upon a misidentification of the text that the Attorney General, pursuant to his "control" authority, is interpreting. No one argues that the word "control" in §821 gives the Attorney General "authority to define diversion based on his view of legitimate medical practice," *ibid.* Rather, that word authorizes the Attorney General to interpret (among other things) the "prescription" requirement of §829. The question then becomes whether the phrase "*legitimate medical purpose*" (which all agree is included in "prescription") is at least *open* to the interpretation announced in the Directive. See *Chevron U. S. A. Inc.*, v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 843 (1984). And of course it is—as the Court effectively concedes two pages earlier: "All would agree, we should think, that the statutory phrase 'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense." *Ante*, at 11 (citing *Chevron*).

explained below, the Directive provides *the most natural* interpretation of the Regulation and of the statute. The Directive thus definitively establishes that a doctor's order authorizing the dispensation of a Schedule II substance for the purpose of assisting a suicide is not a "prescription" within the meaning of §829.

Once this conclusion is established, the other two conclusions in the Directive follow inevitably. Under our reasoning in *Moore*, writing prescriptions that are illegitimate under §829 is certainly not "in the [usual] course of professional practice" under §802(21) and thus not "authorized by this subchapter" under §841(a). See 423 U. S., at 138, 140–141. A doctor who does this may thus be prosecuted under §841(a), and so it follows that such conduct "violates the Controlled Substances Act," 66 Fed. Reg. 56608. And since such conduct is thus not in "[c]ompliance with applicable . . . Federal . . . laws relating to controlled substances," 21 U. S. C. §823(f)(4), and may also be fairly judged to "threaten the public health and safety," §823(f)(5), it follows that "[s]uch conduct by a physician registered to dispense controlled substances *may* 'render his registration . . . inconsistent with the public interest' and therefore subject to *possible* suspension or revocation under 21 U. S. C. [§]824(a)(4)." 66 Fed. Reg. 56608 (emphases added).

II

Even if the Directive were entitled to no deference whatever, the most reasonable interpretation of the Regulation and of the statute would produce the same result. Virtually every relevant source of authoritative meaning confirms that the phrase "legitimate medical purpose"[4]

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[4]This phrase appears only in the Regulation and not in the relevant section of the statute. But as pointed out earlier, the Court does not contest that this is the most reasonable interpretation of the section—regarding it, indeed, as a mere "parroting" of the statute.

does not include intentionally assisting suicide. "Medicine" refers to "[t]he science and art dealing with the prevention, cure, or alleviation of disease." Webster's Second 1527. The use of the word "legitimate" connotes an *objective* standard of "medicine," and our presumption that the CSA creates a uniform federal law regulating the dispensation of controlled substances, see *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U. S. 30, 43 (1989), means that this objective standard must be a federal one. As recounted in detail in the memorandum for the Attorney General that is attached as an appendix to the Directive (OLC Memo), virtually every medical authority from Hippocrates to the current American Medical Association (AMA) confirms that assisting suicide has seldom or never been viewed as a form of "prevention, cure, or alleviation of disease," and (even more so) that assisting suicide is not a "legitimate" branch of that "science and art." See OLC Memo, App. to Pet. for Cert. 113a–130a. Indeed, the AMA has determined that "'[p]hysician-assisted suicide is fundamentally incompatible with the physician's role as a healer.'" *Washington* v. *Glucksberg*, 521 U. S. 702, 731 (1997). "[T]he overwhelming weight of authority in judicial decisions, the past and present policies of nearly all of the States and of the Federal Government, and the clear, firm and unequivocal views of the leading associations within the American medical and nursing professions, establish that assisting in suicide . . . is not a legitimate medical purpose." OLC Memo, *supra*, at 129a. See also *Glucksberg*, *supra*, at 710, n. 8 (prohibitions or condemnations of assisted suicide in 50 jurisdictions, including 47 States, the District of Columbia, and 2 Territories).

In the face of this "overwhelming weight of authority," the Court's admission that "[o]n its own, this understanding of medicine's boundaries is *at least reasonable*," *ante*, at 26 (emphasis added), tests the limits of understate-

ment. The only explanation for such a distortion is that the Court confuses the *normative* inquiry of what the boundaries of medicine *should be*—which it is laudably hesitant to undertake—with the *objective* inquiry of what the accepted definition of "medicine" *is*. The same confusion is reflected in the Court's remarkable statement that "[t]he primary problem with the Government's argument . . . is its assumption that the CSA impliedly authorizes an Executive officer to bar a use simply because it may be inconsistent with *one reasonable understanding* of medical practice." *Ibid.* (emphasis added). The fact that many in Oregon believe that the boundaries of "legitimate medicine" *should be* extended to include assisted suicide does not change the fact that the overwhelming weight of authority (including the 47 States that condemn physician-assisted suicide) confirms that they have not yet been so extended. Not even those of our Eighth Amendment cases most generous in discerning an "evolution" of national standards would have found, on this record, that the concept of "legitimate medicine" has evolved so far. See *Roper* v. *Simmons*, 543 U. S. 551, 564–567 (2005).

The Court contends that the phrase "legitimate medical purpose" *cannot* be read to establish a broad, uniform federal standard for the medically proper use of controlled substances. *Ante*, at 22. But it also rejects the most plausible alternative proposition, urged by the State, that any use authorized under state law constitutes a "legitimate medical purpose." (The Court is perhaps leery of embracing this position because the State candidly admitted at oral argument that, on its view, a State could exempt from the CSA's coverage the use of morphine to achieve euphoria.) Instead, the Court reverse-engineers an approach somewhere between a uniform national standard and a state-by-state approach, holding (with no basis in the CSA's text) that "legitimate medical purpose" refers to *all* uses of drugs unrelated to "addiction and recreational

abuse." *Ante*, at 27. Thus, though the Court pays lipservice to state autonomy, see *ante*, 23–24, its standard for "legitimate medical purpose" is in fact a hazily defined *federal* standard based on its purposive reading of the CSA, and extracted from obliquely relevant sections of the Act. In particular, relying on its observation that the criteria for scheduling controlled substances are primarily concerned with "addiction or abnormal effects on the nervous system," *ante*, at 26–27 (citing 21 U. S. C. §§811(c)(7), 812(b), 811(f), 801a), the Court concludes that the CSA's prescription requirement must be interpreted in light of this narrow view of the statute's purpose.

Even assuming, however, that the *principal* concern of the CSA is the curtailment of "addiction and recreational abuse," there is no reason to think that this is its *exclusive* concern. We have repeatedly observed that Congress often passes statutes that sweep more broadly than the main problem they were designed to address. "[S]tatutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale* v. *Sundowner Offshore Services, Inc.*, 523 U. S. 75, 79 (1998). See also *H. J. Inc.* v. *Northwestern Bell Telephone Co.*, 492 U. S. 229, 248 (1989).

The scheduling provisions of the CSA on which the Court relies confirm that the CSA's "design," *ante*, at 23, is not as narrow as the Court asserts. In making scheduling determinations, the Attorney General must not only consider a drug's "psychic or physiological dependence liability" as the Court points out, *ante*, at 26 (citing 21 U. S. C. §811(c)(7)), but must also consider such broad factors as "[t]he state of current scientific knowledge regarding the drug or other substance," §811(c)(3), and (most notably) "[w]hat, if any, risk there is to the public health," §811(c)(6). If the latter factor were limited to addiction-

related health risks, as the Court supposes, it would be redundant of §811(c)(7). Moreover, in making registration determinations regarding manufacturers and distributors, the Attorney General "shall" consider "such *other* factors as may be relevant to and consistent with the public health and safety," §§823(a)(6), (b)(5), (d)(6), (e)(5) (emphasis added)—over and above the risk of "diversion" of controlled substances, §§823(a)(1), (a)(5), (b)(1), (d)(1), (d)(5), (e)(1). And, most relevant of all, in registering and deregistering *physicians*, the Attorney General "may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest," §823(f); see also §824(a)(4), and in making that determination "shall" consider "[s]uch other conduct which may threaten the public health and safety," §823(f)(5). *All* of these provisions, not just those selectively cited by the Court, shed light upon the CSA's repeated references to the undefined term "abuse." See §§811(a)(1)(A), (c)(1), (c)(4), (c)(5); §§812(b)(1)(A), (b)(2)(A), (b)(3)(A), (b)(4)(A), (b)(5)(A).

By disregarding all these public-interest, public-health, and public-safety objectives, and limiting the CSA to "addiction and recreational abuse," the Court rules out the prohibition of anabolic-steroid use for bodybuilding purposes. It seeks to avoid this consequence by invoking the Anabolic Steroids Control Act of 1990, 104 Stat. 4851. *Ante*, at 27. But the only effect of that legislation is to make anabolic steroids controlled drugs under Schedule III of the CSA. If the only *basis* for control is (as the Court says) "addiction and recreational abuse," dispensation of these drugs for bodybuilding could not be proscribed.

Although, as I have described, the Court's opinion no more defers to state law than does the Directive, the Court relies on two provisions for the conclusion that "[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the

States' police powers," *ante*, at 23—namely the registration provisions of §823(f) and the nonpre-emption provision of §903. Reliance on the former is particularly unfortunate, because the Court's own analysis recounts how Congress amended §823(f) in 1984 in order to *liberate* the Attorney General's power over registration from the control of state regulators. See *ante*, at 14; 21 U. S. C. §823(f); see also Brief for Petitioners 34–35. And the nonpre-emption clause is embarrassingly inapplicable, since it merely disclaims field pre-emption, and affirmatively *prescribes* federal pre-emption whenever state law creates a conflict.[5] In any event, the Directive does not purport to pre-empt state law in any way, not even by conflict pre-emption—unless the Court is under the misimpression that some States *require* assisted suicide. The Directive merely interprets the CSA to prohibit, like countless other federal criminal provisions, conduct that happens not to be forbidden under state law (or at least the law of the State of Oregon).

With regard to the CSA's registration provisions, 21 U. S. C. §§823(f), 824(a), the Court argues that the statute cannot fairly be read to "'hide elephants in mouseholes'" by delegating to the Attorney General the power to determine the legitimacy of medical practices in "'vague terms or ancillary provisions.'" *Ante*, at 20 (quoting *Whitman* v. *American Trucking Assns., Inc.*, 531 U. S. 457, 468 (2001)). This case bears not the remotest resemblance to *Whitman*, which held that "Congress . . . does not alter *the fundamental details* of a regulatory scheme in vague terms or ancillary provisions." *Ibid.* (emphasis added). The Attorney General's power to issue regulations against question-

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[5]Title 21 U. S. C. §903 reads, in relevant part, as follows: "No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter . . . unless there is a positive conflict . . . ."

able uses of controlled substances in no way alters "the fundamental details" of the CSA. I am aware of only four areas in which the Department of Justice has exercised that power to regulate uses of controlled substances *unrelated* to "addiction and recreational abuse" as the Court apparently understands that phrase: assisted suicide, aggressive pain management therapy, anabolic-steroid use, and cosmetic weight-loss therapy. See, *e.g.*, *In re Harline*, 65 Fed. Reg. 5665, 5667 (2000) (weight loss); *In re Tecca*, 62 Fed. Reg. 12842, 12846 (1997) (anabolic steroids); *In re Roth*, 60 Fed. Reg. 62262, 62263, 62267 (1995) (pain management). There is no indication that enforcement in these areas interferes with the prosecution of "drug abuse" as the Court understands it. Unlike in *Whitman*, the Attorney General's *additional* power to address other forms of drug "abuse" does *absolutely nothing* to undermine the central features of this regulatory scheme. Of course it was critical to our analysis in *Whitman* that the language of the provision did not bear the meaning that respondents sought to give it. See 531 U. S., at 465. Here, for the reasons stated above, the provision is most naturally interpreted to incorporate a uniform federal standard for legitimacy of medical practice.[6]

Finally, respondents argue that the Attorney General must defer to state-law judgments about what constitutes legitimate medicine, on the ground that Congress must speak clearly to impose such a uniform federal standard upon the States. But no line of our clear-statement cases

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[6]The other case cited by the Court, *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U. S. 120 (2000), is even more obviously inapt. There we relied on the first step of the *Chevron* analysis to determine that Congress had spoken to the precise issue in question, impliedly repealing the grant of jurisdiction on which the FDA relied. 529 U. S., at 160–161. Here, Congress has not expressly or impliedly authorized the practice of assisted suicide, or indeed "spoken directly" to the subject in any way beyond the text of the CSA.

is applicable here. The canon of avoidance does not apply, since the Directive does not push the outer limits of Congress's commerce power, compare *Solid Waste Agency of Northern Cook Cty.* v. *Army Corps of Engineers*, 531 U. S. 159, 172 (2001) (regulation of isolated ponds), with *United States* v. *Sullivan*, 332 U. S. 689, 698 (1948) (regulation of labeling of drugs shipped in interstate commerce), or impinge on a core aspect of state sovereignty, cf. *Atascadero State Hospital* v. *Scanlon*, 473 U. S. 234, 242 (1985) (sovereign immunity); *Gregory* v. *Ashcroft*, 501 U. S. 452, 460 (1991) (qualifications of state government officials). The clear-statement rule based on the presumption against pre-emption does not apply because the Directive does not pre-empt any state law, cf. *id.*, at 456–457; *Rush Prudential HMO, Inc.* v. *Moran*, 536 U. S. 355, 359 (2002). And finally, no clear statement is required on the ground that the Directive intrudes upon an area traditionally reserved exclusively to the States, cf. *BFP* v. *Resolution Trust Corporation*, 511 U. S. 531, 544 (1994) (state regulation of titles to real property), because the Federal Government has pervasively regulated the dispensation of drugs for over 100 years. See generally Brief for Pro-Life Legal Defense Fund et al. as *Amici Curiae* 3–15. It would be a novel and massive expansion of the clear-statement rule to apply it in a commerce case *not involving pre-emption or constitutional avoidance*, merely because Congress has chosen to prohibit conduct that a State has made a contrary policy judgment to permit. See *Sullivan*, *supra*, at 693.

III

Even if the Regulation did not exist and "prescription" in §829 could not be interpreted to require a "legitimate medical purpose," the Directive's conclusion that "prescribing, dispensing, or administering federally controlled substances . . . by a physician . . . may 'render his registra-

tion . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation under 21 U. S. C. [§]824(a)(4)," 66 Fed. Reg. 56608, would nevertheless be unassailable in this Court.

Sections 823(f) and 824(a) explicitly grant the Attorney General the authority to register and deregister physicians, and his discretion in exercising that authority is spelled out in very broad terms. He may refuse to register or deregister if he determines that registration is "inconsistent with the public interest," 21 U. S. C. §823(f), after considering five factors, the fifth of which is "[s]uch other conduct which may threaten the public health and safety," §823(f)(5). See also *In re Arora*, 60 Fed. Reg. 4447, 4448 (1995) ("It is well established that these factors are to be considered in the disjunctive, i.e., the Deputy Administrator may properly rely on any one or a combination of factors, and give each factor the weight he deems appropriate"). As the Court points out, these broad standards were enacted in the 1984 amendments for the specific purpose of *freeing* the Attorney General's discretion over registration from the decisions of state authorities. See *ante*, at 13.

The fact that assisted-suicide prescriptions are issued in violation of §829 is of course sufficient to support the Directive's conclusion that issuing them may be cause for deregistration: such prescriptions would violate the fourth factor of §823(f), namely "[c]ompliance with applicable . . . Federal . . . laws relating to controlled substances," 21 U. S. C. §823(f)(4). But the Attorney General did not rely solely on subsection (f)(4) in reaching his conclusion that registration would be "inconsistent with the public interest"; nothing in the text of the Directive indicates that. Subsection (f)(5) ("[s]uch other conduct which may threaten the public health and safety") provides an independent, alternative basis for the Directive's conclusion regarding deregistration—provided that the Attorney General has

authority to interpret "public interest" and "public health and safety" in §823(f) to exclude assisted suicide.

Three considerations make it perfectly clear that the statute confers authority to interpret these phrases upon the Attorney General. First, the Attorney General is solely and explicitly charged with administering the registration and deregistration provisions. See §§823(f), 824(a). By making the criteria for such registration and deregistration such obviously ambiguous factors as "public interest" and "public health and safety," Congress implicitly (but clearly) gave the Attorney General authority to interpret those criteria—*whether or not* there is any explicit delegation provision in the statute. "Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Chevron*, 467 U. S., at 844. The Court's exclusive focus on the *explicit* delegation provisions is, at best, a fossil of our pre-*Chevron* era; at least since *Chevron*, we have not conditioned our deferral to agency interpretations upon the existence of explicit delegation provisions. *United States* v. *Mead Corp.*, 533 U. S. 218, 229 (2001), left this principle of implicit delegation intact.

Second, even if explicit delegation were required, Congress provided it in §821, which authorizes the Attorney General to "promulgate rules and regulations . . . relating to the *registration and control* of the manufacture, distribution, and dispensing of controlled substances . . . ." (Emphasis added.) Because "dispensing" refers to the delivery of a controlled substance "pursuant to the lawful order of, a practitioner," 21 U. S. C. §802(10), the deregistration of such practitioners for writing impermissible orders "relat[es] to the registration . . . of the . . . dispensing" of controlled substances, 21 U. S. C. A. §821 (Supp. 2005).

Third, §821 also gives the Attorney General authority to promulgate rules and regulations "relating to the . . . control of the . . . dispensing of controlled substances." As discussed earlier, it is plain that the *ordinary* meaning of "control" must apply to §821, so that the plain import of the provision is to grant the Attorney General rulemaking authority over all the provisions of part C of the CSA, 21 U. S. C. A. §§821–830 (main ed. and Supp. 2005). Registering and deregistering the practitioners who issue the prescriptions necessary for lawful dispensation of controlled substances plainly "relat[es] to the . . . control of the . . . dispensing of controlled substances." §821 (Supp. 2005).

The Attorney General is thus authorized to promulgate regulations interpreting §§823(f) and 824(a), both by implicit delegation in §823(f) and by two grounds of explicit delegation in §821. The Court nevertheless holds that this triply unambiguous delegation cannot be given full effect because "the design of the statute," *ante*, at 18, evinces the intent to grant the Secretary of Health and Human Services exclusive authority over scientific and medical determinations. This proposition is not remotely plausible. The Court cites as authority for the Secretary's exclusive authority two specific areas in which his medical determinations are said to be binding on the Attorney General—with regard to the "scientific and medical evaluation" of a drug's effects that precedes its scheduling, §811(b), and with regard to "the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts," 42 U. S. C. §290bb–2a; see also 21 U. S. C. §823(g) (2000 ed. and Supp. II). See *ante*, at 17–19. Far from establishing a general principle of Secretary supremacy with regard to all scientific and medical determinations, the fact that Congress granted the Secretary specifically defined authority in the areas of scheduling and addiction treatment,

without otherwise mentioning him in the registration provisions, suggests, to the contrary, that Congress envisioned *no* role for the Secretary in that area—where, as we have said, interpretive authority was both implicitly and explicitly conferred upon the Attorney General.

Even if we could rewrite statutes to accord with sensible "design," it is far from a certainty that the Secretary, rather than the Attorney General, ought to control the registration of physicians. Though registration decisions sometimes require judgments about the legitimacy of medical practices, the Department of Justice has seemingly had no difficulty making them. See *In re Harline*, 65 Fed. Reg. 5665; *In re Tecca*, 62 Fed. Reg. 12842; *In re Roth*, 60 Fed. Reg. 62262. But unlike decisions about whether a substance should be scheduled or whether a narcotics addiction treatment is legitimate, registration decisions are not exclusively, or even primarily, concerned with "medical [and] scientific" factors. See 21 U. S. C. §823(f). Rather, the decision to register, or to bring an action to deregister, an individual *physician* implicates all the policy goals and competing enforcement priorities that attend any exercise of prosecutorial discretion. It is entirely reasonable to think (as Congress evidently did) that it would be easier for the Attorney General occasionally to make judgments about the legitimacy of medical practices than it would be for the Secretary to get into the business of law enforcement. It is, in other words, perfectly consistent with an intelligent "design of the statute" to give the Nation's chief law enforcement official, not its chief health official, broad discretion over the substantive standards that govern registration and deregistration. That is *especially* true where the contested "scientific and medical" judgment at issue has to do with the legitimacy of physician-assisted suicide, which ultimately rests, not on "science" or "medicine," but on a naked value judgment. It no more depends upon a "quintessentially medical judg-

men[t]," *ante*, at 20, than does the legitimacy of polygamy or eugenic infanticide. And it requires no particular *medical* training to undertake the objective inquiry into how the continuing traditions of Western medicine have consistently treated this subject. See OLC Memo, App. to Pet. for Cert. 113a–130a. The Secretary's supposedly superior "medical expertise" to make "medical judgments," *ante*, at 19–20, is strikingly irrelevant to the case at hand.

The Court also reasons that, even if the CSA grants the Attorney General authority to interpret §823(f), the Directive does not purport to exercise that authority, because it "does not undertake the five-factor analysis" of §823(f) and does not "on its face purport to be an *application* of the registration provision in §823(f)." *Ante*, at 14 (emphasis added). This reasoning is sophistic. It would be improper—indeed, *impossible*—for the Attorney General to "undertake the five-factor analysis" of §823(f) and to "appl[y] the registration provision" outside the context of an actual enforcement proceeding. But of course the Attorney General may issue regulations to clarify his interpretation of the five factors, and to signal how he will apply them in future enforcement proceedings. That is what the Directive plainly purports to do by citing §824(a)(4), and that is why the Directive's conclusion on deregistration is couched in conditional terms: "Such conduct by a physician . . . *may* 'render his registration . . . inconsistent with the public interest' and therefore subject to *possible* suspension or revocation under 21 U. S. C. [§]824(a)(4)." 66 Fed. Reg. 56608 (emphasis added).

It follows from what we have said that the Attorney General's authoritative interpretations of "public interest" and "public health and safety" in §823(f) are subject to *Chevron* deference. As noted earlier, the Court does not contest that the absence of notice-and-comment procedures for the Directive renders *Chevron* inapplicable. And there is no serious argument that "Congress has directly

spoken to the precise question at issue," or that the Directive's interpretations of "public health and safety" and "inconsistent with the public interest" are not "permissible." *Chevron*, 467 U. S., at 842–843. On the latter point, in fact, the condemnation of assisted suicide by 50 American jurisdictions supports the Attorney General's view. The Attorney General may therefore weigh a physician's participation in assisted suicide as a factor counseling against his registration, or in favor of deregistration, under §823(f).

In concluding to the contrary, the Court merely presents the conclusory assertion that "it is doubtful the Attorney General could cite the 'public interest' or 'public health' to deregister a physician simply because he deemed a controversial practice permitted by state law to have an illegitimate medical purpose." *Ante*, at 17. But why on earth not?—especially when he has interpreted the relevant statutory factors in advance to give fair warning that such a practice is "inconsistent with the public interest." The Attorney General's discretion to determine the public interest in this area is admittedly broad—but certainly no broader than other congressionally conferred Executive powers that we have upheld in the past. See, *e.g.*, *National Broadcasting Co.* v. *United States*, 319 U. S. 190, 216–217 (1943) ("public interest"); *New York Central Securities Corp.* v. *United States*, 287 U. S. 12, 24–25 (1932) (same); see also *Mistretta* v. *United States*, 488 U. S. 361, 415–416 (1989) (SCALIA, J., dissenting).

* * *

In sum, the Directive's first conclusion—namely that physician-assisted suicide is not a "legitimate medical purpose"—is supported both by the deference we owe to the agency's interpretation of its own regulations and by the deference we owe to its interpretation of the statute. The other two conclusions—(2) that prescribing controlled

drugs to assist suicide violates the CSA, and (3) that such conduct is also "inconsistent with the public interest"—are inevitable consequences of that first conclusion. Moreover, the third conclusion, standing alone, is one that the Attorney General is authorized to make.

The Court's decision today is perhaps driven by a feeling that the subject of assisted suicide is none of the Federal Government's business. It is easy to sympathize with that position. The prohibition or deterrence of assisted suicide is certainly not among the enumerated powers conferred on the United States by the Constitution, and it is within the realm of public morality *(bonos mores)* traditionally addressed by the so-called police power of the States. But then, neither is prohibiting the recreational use of drugs or discouraging drug addiction among the enumerated powers. From an early time in our national history, the Federal Government has used its enumerated powers, such as its power to regulate interstate commerce, for the purpose of protecting public morality—for example, by banning the interstate shipment of lottery tickets, or the interstate transport of women for immoral purposes. See *Hoke* v. *United States*, 227 U. S. 308, 321–323 (1913); *Lottery Case*, 188 U. S. 321, 356 (1903). Unless we are to repudiate a long and well-established principle of our jurisprudence, using the federal commerce power to prevent assisted suicide is unquestionably permissible. The question before us is not whether Congress *can* do this, or even whether Congress *should* do this; but simply whether Congress *has* done this in the CSA. I think there is no doubt that it has. If the term "*legitimate* medical purpose" has any meaning, it surely excludes the prescription of drugs to produce death.

For the above reasons, I respectfully dissent from the judgment of the Court.

SUPREME COURT OF THE UNITED STATES

No. 04–623

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL., PETITIONERS *v.* OREGON ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

[January 17, 2006]

JUSTICE THOMAS, dissenting.

When Angel Raich and Diane Monson challenged the application of the Controlled Substances Act (CSA), 21 U. S. C. §801 *et seq.*, to their purely intrastate possession of marijuana for medical use as authorized under California law, a majority of this Court (a mere seven months ago) determined that the CSA effectively invalidated California's law because "the CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, *and in what manner*." *Gonzales* v. *Raich*, 545 U. S. ___, ___ (2005) (slip op., at 24) (emphasis added). The majority employed unambiguous language, concluding that the "manner" in which controlled substances can be utilized "for medicinal purposes" is one of the "core activities regulated by the CSA." *Id.*, at ___ (slip op., at 25). And, it described the CSA as "creating a comprehensive framework for regulating the production, distribution, and possession of . . . 'controlled substances,'" including those substances that "'have a useful and legitimate medical purpose,'" in order to "foster the beneficial use of those medications" and "to prevent their misuse." *Id.*, at ___ (slip op., at 21).

Today the majority beats a hasty retreat from these conclusions. Confronted with a regulation that broadly requires all prescriptions to be issued for a "legitimate

medical purpose," 21 CFR §1306.04(a) (2005), a regulation recognized in *Raich* as part of the Federal Government's "closed . . . system" for regulating the "manner" in "which controlled substances can be utilized for medicinal purposes," 545 U. S., at ___, ___ (slip op., at 10, 24), the majority rejects the Attorney General's admittedly "at least reasonable," *ante*, at 26, determination that administering controlled substances to facilitate a patient's death is not a "'legitimate medical purpose.'" The majority does so based on its conclusion that the CSA is only concerned with the regulation of "medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Ante*, at 23. In other words, in stark contrast to *Raich*'s broad conclusions about the scope of the CSA as it pertains to the medicinal use of controlled substances, today this Court concludes that the CSA is merely concerned with fighting "'drug abuse'" and only insofar as that abuse leads to "addiction or abnormal effects on the nervous system."[1] *Ante*, at 26.

The majority's newfound understanding of the CSA as a statute of limited reach is all the more puzzling because it rests upon constitutional principles that the majority of the Court rejected in *Raich*. Notwithstanding the States' "'traditional police powers to define the criminal law and to protect the health, safety, and welfare of their citizens,'" 545 U. S., at ___, n. 38 (slip op., at 27, n. 38), the *Raich* majority concluded that the CSA applied to the intrastate possession of marijuana for medicinal purposes authorized by California law because "Congress could have rationally" concluded that such an application was necessary to the

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[1]The majority does not expressly address whether the ingestion of a quantity of drugs that is sufficient to cause death has an "abnormal effec[t] on the nervous system," *ante*, at 25, though it implicitly rejects such a conclusion.

regulation of the "larger interstate marijuana market." *Id.*, at ___, ___ (slip op., at 28, 30). Here, by contrast, the majority's restrictive interpretation of the CSA is based in no small part on "the structure and limitations of federalism, which allow the States '"great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."'" *Ante*, at 23 (quoting *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 475 (1996), in turn quoting *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U. S. 724, 756 (1985)). According to the majority, these "background principles of our federal system . . . belie the notion that Congress would use . . . an obscure grant of authority to regulate areas traditionally supervised by the States' police power." *Ante*, at 28.

Of course there is nothing "obscure" about the CSA's grant of authority to the Attorney General. *Ante*, p. ___ (SCALIA, J., dissenting). And, the Attorney General's conclusion that the CSA prohibits the States from authorizing physician assisted suicide is admittedly "at least reasonable," *ante*, at 26 (opinion of the Court), and is therefore entitled to deference. *Ante*, at 6–7 (SCALIA, J., dissenting). While the scope of the CSA and the Attorney General's power thereunder are sweeping, and perhaps troubling, such expansive federal legislation and broad grants of authority to administrative agencies are merely the inevitable and inexorable consequence of this Court's Commerce Clause and separation-of-powers jurisprudence. See, *e.g.*, *Raich*, *supra*; *Whitman* v. *American Trucking Assns., Inc.*, 531 U. S. 457 (2001).

I agree with limiting the applications of the CSA in a manner consistent with the principles of federalism and our constitutional structure. *Raich*, *supra*, at ___ (THOMAS, J., dissenting); cf. *Whitman*, *supra*, at 486–487 (THOMAS, J., concurring) (noting constitutional concerns with broad delegations of authority to administrative agencies). But that is now water over the dam. The rele-

vance of such considerations was at its zenith in *Raich*, when we considered whether the CSA could be applied to the intrastate possession of a controlled substance consistent with the limited federal powers enumerated by the Constitution. Such considerations have little, if any, relevance where, as here, we are merely presented with a question of statutory interpretation, and not the extent of constitutionally permissible federal power. This is particularly true where, as here, we are interpreting broad, straightforward language within a statutory framework that a majority of this Court has concluded is so comprehensive that it necessarily nullifies the States' "'traditional . . . powers . . . to protect the health, safety, and welfare of their citizens.'"[2] *Raich*, *supra*, at ___, n. 38 (slip op., at 27, n. 38). The Court's reliance upon the constitutional principles that it rejected in *Raich*—albeit under the guise of statutory interpretation—is perplexing to say the least. Accordingly, I respectfully dissent.

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[2]Notably, respondents have not seriously pressed a constitutional claim here, conceding at oral argument that their "point is not necessarily that [the CSA] would be unconstitutional." Tr. of Oral Arg. 44. In any event, to the extent respondents do present a constitutional claim, they do so solely within the framework of *Raich*. Framed in this manner, the claim must fail. The respondents in *Raich* were "local growers and users of state-authorized, medical marijuana," who stood "outside the interstate drug market" and possessed "'medicinal marijuana . . . not intended for . . . the stream of commerce.'" 545 U. S., at ___, ___, (slip op., at 5, 16) (THOMAS, J., dissenting). Here, by contrast, the respondent-physicians are active participants in the interstate controlled substances market, and the drugs they prescribe for assisting suicide have likely traveled in interstate commerce. If the respondents in *Raich* could not sustain a constitutional claim, then *a fortiori* respondents here cannot sustain one. Respondents' acceptance of *Raich* forecloses their constitutional challenge.